

DIVERGING AGAINST ALL ODDS? REGULATORY PATHS IN EMBRYONIC STEM CELL RESEARCH ACROSS WESTERN EUROPE --- APPENDIX: Fs/QCA CALIBRATION

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APPENDIX: Fs/QCA CALIBRATION

The appendix presents the measurement and calibration of the dependent and independent variables modeled in the Fs/QCA analysis.

A. OUTCOME: EMBRYONIC STEM CELL RESEARCH (ESCR) REGULATIONS IN WESTERN EUROPE

In this analysis, our dependent variable, the outcome in Fs/QCA terminology, is the policies on ESCR adopted in the major Western European Countries (Portugal, Spain, France, Italy, Belgium, The Netherlands, Germany, Switzerland, The United Kingdom, Denmark, Sweden, Norway, Finland, Iceland, Greece). We are considering all the legally binding and explicit policy decisions that were made on ESCR in these countries. Accordingly, we have excluded two major European countries – Austria and Ireland. In these countries, no binding and explicit regulation on ESCR has been elaborated so far. As the literature points out (Engeli et al. 2012; Fink 2008; Bleiklie et al. 2004; Montpetit et al. 2008), one cannot assume that non-decisions on ESCR necessarily correspond to *de facto* restrictive or permissive policies. In Ireland, non-decisions on ESCR have resulted into legal and scientific uncertainty. For a long time, no research on embryonic stem cells research at all was conducted in Ireland. A couple of years ago, some Universities such as Trinity College have decided to allow some ESCR and have therefore developed their own self-regulation. In the case of Austria, there are no binding explicit regulations of ESCR and there are also no binding court decisions that would confirm the opinion of the Austrian Bioethics

Commission from 2009 (see Human Embryonic Stem Cells: Opinion of the Austrian Bioethics Commission, March 2009, <http://www.bka.gv.at/>) on how to interpret the Reproductive Medicine Act from 2004 and the Medicinal Products Import Act from 2002. As in this analysis, we are exclusively focusing on explicit and binding policy decisions on ESCR, we have thus excluded these two countries.

The unit of analysis being the policy decision, our N covered 22 decisions in 15 countries. 9 countries have only made, so far, one single decision on ESCR while 6 countries have taken more than one decision (The United Kingdom: 2; Spain: 2; Greece: 2; Norway: 3; The Netherlands: 2; Switzerland: 2).

We conceptualize medical and scientific autonomy as the degree of freedom granted to doctors and researchers to conduct ESCR and the conditions under which research should be conducted (Engeli et al. 2012a). Three regulatory components are taken into account: (Indicator 1) the type of embryo that can be used for ESCR, (Indicator 2) the grounds for conducting research and (Indicator 3) the approval procedure for research.

Indicator 1: First, the regulations differ with respect to the type of embryo that can be used to derive embryonic stem cells lines. Permissive regulation allows for creating embryos specifically for ESCR and the derivation of stem cell lines (score 3). Intermediate policies only allow for conducting research on leftover embryos resulting from the termination of IVF treatment or then limit research to embryos and embryos imported from other countries (2). Finally, restrictive policies only allow research conducted on imported stem cell lines (1) or ban any kind of ESCR research (0).

Indicator 2: Second, regarding the grounds for research, permissive regulations do not constrain research to specific grounds (score 3), whereas restrictive ones ban research entirely (0) or with

the exception of a limited number of therapeutic ground research (1). Intermediate regulation spells out a series of permitted grounds in an explicit way (2).

Indicator 3: Third, permissive regulatory frameworks does not require any general authorization to conduct research (3), while intermediate regulation requires a general authorization for being allowed to conduct ESCR (2), but do not impose an approval procedure specific to each research project as restrictive regulatory frameworks require (1). Finally, research ban is assigned the score of 0.

We built up an additive index of the three indicators ((Indicator 1 + Indicator 2+ Indicator 3)/3) with equal weighting – the index has a minimum of 0 and a maximum of 3. We have then rescaled the index into the 4-value fuzzy-set score as follows: total bans are assigned a fuzzy-set score of 0 (index score: 0.00), restrictive regulations a score of 0.33 (index scores: 1.00, 1.33), intermediate regulations a score of 0.67 (index scores 2.00, 2.33) and permissive regulation a score of 1 (index score: 3.00). Table A1 below displays the detailed coding of the dependent variable.

Table A1: Coding of the Dependent Variable

INDICATORS	PERMISSIVE SCORE=3	INTERMEDIATE SCORE=2	RESTRICTIVE SCORE=1	BAN SCORE=0
EMBRYO TYPE	Creation of embryo <i>UK 2000, UK 2008; Iceland 2008; Belgium 2003; Sweden 2005</i>	Leftover embryo <i>France 2004; Spain 2003; Spain 2006; Norway 2007; Denmark 2003; Finland 1998; Greece 2002; Greece 2005; The Netherlands 2002; The Netherlands 2007; Portugal 2006</i>	Imported stem cell lines <i>Switzerland 2003; Germany 2002</i>	Ban <i>Switzerland 1998; Italy 2004; Norway 2000, Norway 2003</i>
GROUND	General permission <i>UK 2000, UK 2008; Iceland 2008; Belgium 2003; Sweden 2005; The Netherlands 2002; The Netherlands 2007</i>	Explicit mention of specific grounds <i>Finland 1998; Switzerland 2003; Greece 2002; Greece 2005; Portugal 2006</i>	Therapeutic grounds only <i>France 2004; Germany 2002; Spain 2003; Spain 2006; Norway 2007; Denmark 2003</i>	Ban <i>Switzerland 1998; Italy 2004; Norway 2000, Norway 2003</i>
PROCEDURE	General approval procedure <i>UK 2000, UK 2008; Iceland 2008; Belgium 2003; Sweden 2005</i>	Specific approval procedure for each type of research <i>Finland 1998; Greece 2002; Greece 2005; The Netherlands 2002; The Netherlands 2007; Portugal 2006</i>	Specific approval procedure for each research project <i>Switzerland 2003; France 2004; Germany 2002; Spain 2003; Spain 2006; Norway 2007; Denmark 2003</i>	Ban <i>Switzerland 1998; Italy 2004; Norway 2000, Norway 2003</i>
Sources: The United Kingdom: Larsen et al. 2012; Spain: Chaques and Palau 2012; The Netherlands: Timmermans and Breemans 2012; Denmark: Albaek et al. 2012; Iceland, Italy, Belgium, Sweden, France, Norway, Finland, Greece, Portugal, Switzerland, Germany, Norway: own coding				

B. CONDITIONS

“PARTY POLITICS” CONDITIONS

Strength of the religious parties

Religious parties have not been the major members of governmental coalitions in most Western European countries since the beginning of the regulation process on ESCR. Measuring their strength through government participation would not have provided a condition with enough variation. Nevertheless, they might have still some influence on designing and/or vetoing ESCR regulation through parliamentary representation. Therefore, we have decided to capture their impact through the total percentage of seats held by Christian Democrats and other religious parties in the lower or single House at the time of the law adoption. We rely on Armingeon et al. (2011)’s categorization of religious parties in Western Europe. As the number of cases is small, it was not methodologically feasible to keep the original scale that was going from 0% to 36.6%. Instead, we have calibrated it into a 4-value fuzzy-set condition as follows. Religious parties holding less than 10% of seats are calibrated to a fuzzy-set score of 0 as their low representation in parliament does not provide them with a strong capacity to influence the decision-making process in a decisive way on their own. Religious parties holding more than 20% of parliamentary seats represent a powerful parliamentary group that plays a preponderant role in the bargaining process over the regulation.

TABLE A2: CALIBRATION OF THE “RELIGIOUS PARTIES” CONDITION

% PARLIAMENTARY SEATS	FUZZY-SET SCORE
0% to 10%	0
10.01 % to 15%	0.33
15.01% to 20%	0.67
20.01% to 36.6%	1
Source: Armingeon et al. (2011)	

Leftist Cabinet

In contrary to the Christian Democrats, the Social Democrats have been important members of cabinets across Western Europe over the last two decades, sometimes in coalition with other leftist parties. Accordingly, they might not only have bargaining power over the designing of the regulation, but might actually choose the design of the regulation. For this reason, we have selected the Armingeon et al. (2011)'s indicator capturing the total % of the cabinet positions held by Social-Democratic and other leftist parties at the time when the law was adopted. The original indicator is going from 0 cabinet position to 100%, with four important gaps - between 0% and 22.25%, between 32.16% and 50%, 55.56% and 78.95%, as well as between 79.18% and 100%. A direct conversion would not capture this important qualitative gap. Accordingly, we have opted for a 4-value fuzzy-set condition instead and better account for the qualitative difference in being a minor member of a cabinet coalition, a major member or being in full power.

TABLE A3: CALIBRATION OF THE “LEFTIST CABINET” CONDITION

% CABINET POSITION	FUZZY-SET SCORE
0 %	0 “not in power”
22.25% to 32.16%	0.33 “minor coalition member”
50% to 79.18%	0.67 “major coalition member”
100%	1 “in full power”
Source: Armingeon et al. (2011)	

“PUBLIC OPINION” CONDITIONS

Attitude toward the human embryo

There is no public opinion data on ESCR available that would cover the whole time period and the entire set of countries included in our study. The best proxy available is the attitude toward abortion. As ESCR addresses the issue of the status of the human embryo is a similar way than

the abortion issue does (i.e. the derivation of stem cells implies the destruction of the embryo), we have thus decided to rely on public opinion measure of attitudes toward abortion as a proxy. We rely on the 5-wave World Value Survey data and capture the aggregate proportion of citizens who considers abortion “as never justifiable” (aggregation of the 1 to 3 positions on the original 10-point scale), which goes from 7.9% to 51.60%. We recalibrated into a 4-value fuzzy-set condition and set the cutting-off points every 10.9% increase (i.e. (maximum value – minimum value)/4) as the original quantitative displays a normal distribution. The World Value Survey dataset is a 5-wave dataset. We used data from the most recent survey wave immediately preceding the relevant policy decision year.

TABLE A4: CALIBRATION OF THE “ATTITUDE TOWARD THE HUMAN EMBRYO” CONDITION

% OF RESPONDENTS CONSIDERING ABORTION AS “NEVER JUSTIFIABLE”	FUZZY-SET SCORE
7.2 % to 18.8%	0 “permissive attitude toward embryo”
18.81% to 29.8%	0.33 “rather permissive attitude toward embryo”
29.81% to 40.7%	0.67 “rather conservative attitude toward embryo”
40.71% to 51.6%	1 “conservative attitude toward embryo”
Source: World Values Survey	

Church Attendance

There is no annual data regarding church attendance available that covers the entire time period and set of countries included in our study. In a similar way as for ‘opinion on human embryo’, we therefore rely on the 5-wave World Value Survey data and use an indicator of the aggregate proportion of citizens who attend church services at least once per month, which goes from 7.9% to 54.2%. We recalibrated into a 4-value fuzzy-set condition and set the cutting-off points every 11.6% increase (i.e. (maximum value – minimum value)/4). The World Value Survey dataset is a

5-wave dataset. We used data from the most recent survey wave immediately preceding the relevant policy decision year.

TABLE A5: CALIBRATION OF THE “CHURCH ATTENDANCE” CONDITION

% OF RESPONDENTS ATTENDING CHURCH SERVICE AT LEAST ONCE PER MONTH	FUZZY-SET SCORE
7.9 % to 19.5%	0 “secular society”
19.51% to 31.1%	0.33 “rather secular society”
31.11% to 42.7%	0.67 “rather religious society”
42.71% to 54.2%	1 “religious society”
Source: World Values Survey	

Attitude toward science advance

There is no public opinion data on attitudes toward scientific advancement available that would cover the entire time period and set of countries included in our study. We thus rely also on the 5-wave World Value Survey data and use an indicator of the proportion of respondents who consider that “in the long run, the scientific advances we are making will help mankind”. As science advance data are more finely gradated than the embryo and church attendance data, we recalibrated into a 6-value fuzzy-set condition (instead of a 4-value condition) and set the cutting-off points every 8.45% increase (i.e. (maximum value – minimum value)/4). The World Value Survey dataset is a 5-wave dataset. We used data from the most recent survey wave immediately preceding the relevant policy decision year.

TABLE A6: CALIBRATION OF THE “ATTITUDE TOWARD SCIENCE ADVANCE” CONDITION

% OF RESPONDENTS CONSIDERING SCIENCE ADVANCE AS “HELPFUL FOR MANKIND”	FUZZY-SET SCORE
33.8 % to 42.5%	0 “mistrusting attitude toward science advance”
42.3% to 50.7%	0.2 “rather mistrusting attitude toward science advance”

50.8% to 59.2%	0.4 “rather mistrusting attitude toward science advance”
59.2% to 67.6%	0.6 “rather trusting attitude toward science advance”
67.7% to 76.1%	0.8 “rather trusting attitude toward science advance”
76.2% to 84.5%	1 “trusting attitude toward science advance”
Source: World Values Survey	

“VALUE-DRIVEN PATH-DEPENDENCE” CONDITION

The impact of prior ART regulation is measured through the medical autonomy granted to physicians to decide upon both the technology to be used and the conditions to be applied to treatment (Bleiklie *et al.* 2004; Engeli *et al.* 2012; Montpetit *et al.* 2007). The coding of ART is based on our previous research and was done as follow: ART techniques are *permissively* regulated (fuzzy-set score 1) if they are not subjected to any substantial restriction (that is, are generally permitted) but might be conditioned by licensing/reporting procedures. The regulation is qualified as *intermediate* (score 0.67) if some light restrictions are imposed. ART techniques are *restrictively* regulated (score 0.33) if their use is severely constrained. Finally, they could be outright *banned* (score 0). We used the most recent policy decision on ART that was immediately preceding the relevant policy decision on ESCR.

TABLE A7: CALIBRATION OF THE “VALUE-DRIVEN PATH DEPENDENCE” CONDITION

PERMISSIVE SCORE: 1	INTERMEDIATE SCORE: 0.67	RESTRICTIVE SCORE: 0.33	BAN SCORE: 0
Belgium Finland Greece02 Greece05 Iceland08 Netherlands07 Portugal06 Sweden05	Italy Spain06 Netherlands02	Denmark France Spain03	Germany Norway00 Norway03 Norway07 Switzerland 03 Switzerland 98

United Kingdom 00			
United Kingdom 08			
Sources: The United Kingdom: Larsen et al. 2012; Spain: Chaques and Palau 2012; The Netherlands: Timmermans and Breemans 2012; Denmark: Albaek et al. 2012; Iceland, Italy, Belgium, Sweden, France, Norway, Finland, Greece, Portugal, Switzerland, Germany, Norway: own coding			