DIVERGING AGAINST ALL ODDS? REGULATORY PATHS IN EMBRYONIC STEM CELL RESEARCH ACROSS WESTERN EUROPE

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DIVERGING AGAINST ALL ODDS? REGULATORY PATHS IN EMBRYONIC STEM CELL RESEARCH ACROSS WESTERN EUROPE

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ABSTRACT

An interest-driven account of Embryonic Stem Cell Research would, given the considerable financial and scientific concerns, likely predict regulations to converge towards permissive policies. However, across Western Europe, national regulations of embryonic stem-cell research vary considerably, from general bans to permissive policies. There is a lack of systematic accounting for the non-convergence, and the sparse attempts at explanation are contradictory. Drawing on qualitative comparative analysis and configurational causality, we assess the interaction of a number of explanatory factors. Our empirical analysis reveals the importance of one factor in particular, path-dependence, insofar as prior policies on assisted reproduction exert a strong and systematic effect on the subsequent regulation of ESCR.

KEY-WORDS: Policy Convergence, Path-Dependency, Policy Change, Morality Policy, ESCR, Qualitative Comparative Analysis
INTRODUCTION

Since the early stages in the development of human biotechnology, the differences in regulations across Western Europe intrigued and puzzled comparative public policy scholars. Regulatory paths on human biotechnology diverge substantially and this is also the case for regulating Embryonic Stem Cell Research (ESCR). Given the economic and scientific potential of human biotechnology and the increased international competition in R&D activities (National Science Board 2012; Ernest & Young 2011), purely economic and interest-driven accounts of policy trajectory would predict minimal state regulation combined with strong promotional activities (Banchoff 2005: 204; Tiberghien 2009). However, while some countries - in Asia (e.g. India, Singapore, South Korea) and Europe (Belgium, the UK) – as well as some American States have adopted minimal regulations, other countries, such as France, Germany or Italy, have opted for a highly restrictive regulatory framework to govern ESCR. The convergence hypothesis arguing that the increased international scientific and economic competition would make state regulations converge towards minimal regulation has therefore proven to be wrong with respect to ESCR in Western Europe. The question then arises as to how to explain that policies have not converged across countries after two decades of ECRS research.

Our contribution sheds some light, not on why policies converge, but on why policies don’t converge when one would expect them to do so. The literature on policy diffusion has spent a great deal of time on showing and explaining why policies converge. It has only recently moved toward investigating why policy diffusion does not necessarily result into policy convergence (Knill 2005; Radaelli 2005; Brooks 2007). For biomedical policies, Banchoff (2005) and Jasanoff (2005) have argued that previous policies on embryo research and assisted reproduction explain the lack of convergence. Banchoff’s (2005) through small-N case study comparison has shown that negative policy feedback leads to policy stability or only incremental change. Other comparative studies have resulted in competing explanations for the variation in embryo research

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or ECRS, such as actor-networks, political cleavages, religious values or attitudes towards science (Fink 2008; Gottweis et al. 2009; Bleiklie et al. 2004; Montpetit et al. 2007).

These contradictory results reveal the need for systematic, comparative research that attempts to explain the lack of convergence in regulatory approaches for ESCR (see Engeli et al. 2012a). In most studies, the hypotheses are not tested systematically, beyond the comparison of a limited number of qualitative case studies and cover too short a period in order to actually investigate policy trajectory (see Banchoff 2005). This article contributes to a systematic analysis of how the principal explanatory factors evoked in the literature jointly lead to diverging regulations.

Drawing on Comparative Qualitative Analysis methodology (QCA, Ragin 2000, 2008), we cover 22 regulations of ESCR in Western Europe between 1998 and 2011. Taking the regulation as the unit of analysis, we investigate how value-driven path dependence in combination with party politics and public opinion, two other prominent factors evoked in the literature, lead to diverging regulatory paths in the case of ESCR.

Theoretical framework: Party politics, public opinion or path-dependency?

Comparative studies on human biotechnology have relied on the policy process theories, historical institutionalism, religion and politics and morality politics literatures. Given the variety of theoretical approaches used in the research, the findings have been contradictory and many explanations have proven to be at best weak. Among the various factors evoked in the literature, our analysis focuses on the three approaches that have been most prominent to explain the regulation of human biotechnology in Western Europe: path-dependency, party politics and public opinion.

PATH-DEPENDENCY EXPLANATION
A first path to explaining current ESCR policies looks at past policy experiences. Path dependency (Pierson 2000, 2006) or policy heritage (Rose and Davis 1993) approaches are thus of particular relevance. More ‘advanced’ techniques such as ESCR can easily be assimilated to earlier debates and policies on ART and embryo research (Banchoff 2005; Jasanoff 2005). Banchoff’s work has successfully demonstrated that past policies on embryo research impacted ESCR policies in Germany and the United Kingdom. They influenced not only the actor constellation, but also the “terms of policy controversy” (Banchoff 2005: 211). In line with his findings, first, we argue that there is a lock-in effect related to the considerable cost of debating ‘moral’ policy issues. Debating over ESCR strongly polarizes political actors, and also potentially divides political parties and governmental coalitions. Thus, sticking to an already established consensus prevents from reopening any policy debate and reduces the odds of severe internal divide within political parties or governmental coalitions (Banchoff 2005: 209-211). Furthermore, policies already in place have an impact on actor constellations. They give a comparative advantage to those defending the status quo in comparison to forces seeking fundamental policy change (Pierson 2000; Banchoff 2005: 208-209). If during the process of regulating assisted reproductive technologies, medical and research interests have established privileged networks with key administrative political actors resulting in policies favoring, instead of limiting, assisted reproductive technologies, these policies strengthen the already established privileged relationship and give research and medical interests an important say in further developing ART-related policies. To the contrary, if medical and research interests had to accept more restrictions on assisted reproductive technology than they would have wished for, their adversaries who “won” the first round of policy making will be able to mobilize additional resources in the form of the already established norms – i.e. constitutional values or policy frames (see Banchoff 2005: 208-209). Our first hypothesis, therefore, uses past policies as explanatory variable:
HI: The more severely prior policies restricted assisted reproductive technologies, the more likely are severe restrictions on embryonic stem-cell research.

PARTY POLITICS EXPLANATION

Qualitative case studies on the impact of past policy frames on ECRS or other biomedical issues focus exclusively on cases where a strong politicization of the issue can be observed. However, as the most recent research on morality policy demonstrates, the degree of politicization varies considerably depending on the political cleavages characterizing a political system. First, the comparative literature on biomedicine pointed to the importance of partisan politics, but argued that there is no clear cut connection between the composition of the government and the policy outcome (Varone et al. 2006). The most recent research on morality policy successfully revisited this argument. Engeli, Green-Pedersen and Larsen (2012b) show that because morality issues touch upon basic questions of the beginning and the end of life, whether the religious cleavage structures a party system or not, is an important factor for understanding the “conflict definition” of morality policy issues. In other words, the presence of Christian Democratic parties or a Conservative party with religious ties is crucial for understanding policy-making processes for morality policies. Indeed, the secular vs. the religious world, as the authors demonstrate, generate different agenda-setting patterns and conflict definitions. In the religious world compared to the secular world, as Engeli et al. (2012b) demonstrate, embryo and ESCR are more likely to be politicized. We argue that Christian Democrats in particular are likely to have an interest in the politicization of ESCR. In order to broaden their electoral appeal in a strongly secularized environment, for many issues parties with religious ties would opt for policy solutions that are not necessarily based on religious values; however, for the issue of ESCR, it is more likely that they adopt an unsecular strategy, trying to appeal to their core religious voters. Given the challenge of adapting to the process of secularization without losing their religious identity and core electoral
base, the issue of ESCR is an opportunity to reassert their religious identity and recapture
attention to religious themes. Christian Democratic parties would not, however, opt for a strategy
of politicization in order to strengthen their profile, if such a strategy might put in peril a
governmental coalition in which they presently participate. If in the religious world the
politicization is more likely, we can also speculate about how the presence of Christian
Democrats and the composition of government might influence policy outcomes. Given the
religious dimension of the issue, once ESCR has emerged onto the political agenda, Christian
Democrats have little choice but to mobilize for policies that protect “the beginning of life”.
Hence they will advocate restrictive policies or perhaps even total bans. Drawing on the recent
literature on morality issues, we thus formulate a first hypothesis regarding the impact of party
politics:

**H2: If religious cleavages characterize the party system, policies are more likely to turn out
restrictive.**

The left-right cleavage is also of relevance for understanding policy outcomes for ESCR (Fink
2008: 1635). While, at the beginning of the biotechnology revolution, biomedical issues were
sometimes associated with biotechnology and its impact on the environment in general
(Rothmayr and Serdült 2004; Rothmayr and Ramjoué 2004), political debates over the last two
decades have followed separate paths. Hence, in its early stages of policy-making in the 1980s, a
resistance to biomedical developments by leftist parties could be observed. However, because of
the connection of ESCR to the abortion issue and leftist parties, generally having a secular
character, advocating for pro-choice positions in the case of abortion (McBride Stetson 2001),
leftist parties will tend to seek policies that are friendly towards scientific research. As Fink’s
analysis shows, after the ECSR research breakthrough leftist parties tended to adopt liberal laws
on embryo research, while prior to the breakthrough their policy record was more mixed (Fink
2008: 1641-1642). In the case of ESCR, we would accordingly expect them to advocate for less restrictive policies than Conservative or Christian Democratic parties.

**H3: The stronger left-wing parties, the more likely are permissive policies.**

**PUBLIC OPINION EXPLANATION**

There is a long tradition in democratic theory that emphasizes the impact of public opinion (Berry et al. 1998; Dahl 1989; Page and Shapiro 1983) and recent research on policy change has shown that political leaders are influenced by public majority while making policy choices (Burstein and Lincoln 2002; Soroka and Wlezien 2010). Within the comparative literature on biomedicine and biotechnology, besides institutional factors in terms of past policy choices and partisan explanations, public opinion broadly defined as attitudes, beliefs and opinions on political and social issues, has also emerged as a prominent explanation for policy outcomes (Jasanoff 2005, Gottweis 1998; 2006; Bernauer 2003; Fink 2008). The findings on the importance of public opinion for biomedical policies are in line with recent research results on the public opinion – public policy nexus over the last decades: public opinion does matter for explaining policy outcomes and policy change (Burstein 1998; Burstein and April 2002; Burstein and Lincoln 2002; Soule 2004; Soroka and Wlezien 2010; Brooks and Manza 2007; Stimson et al. 1995).

In the case of biomedicine, two types of values or attitudes have been identified to have an impact: religious values and attitudes towards science. Namely, Fink’s comparative quantitative analysis of embryo research laws points out the importance of religious values for explaining embryo research laws together with partisan explanations (Fink 2008). While his theoretical argument is based on the influence of the Catholic Church as an interest group, the literature on morality policy more largely suggests that religious values have an impact on policy debates and policy outcomes (Mooney 2001). As has been demonstrated for abortion, citizens that cherish
religious values are more likely to adhere to a pro-life than a pro-choice position (Weisberg 2005). Equally for embryonic stem-cell research, we can expect that secular citizens will be more in favor of permissive solutions, while religious citizens prefer more restrictive policies that guarantee a stronger protection of what they see to be the beginning of life.

**H4**: The more the general public cherishes religious values, the more likely is the adoption of policies imposing severe restrictions on ESCR.

In terms of attitudes towards science, Nielsen et al. (2002) have argued that there are two types of resistance towards biotechnology, traditional blue (religious) and modern green (environmental) forms of resistance. As various case studies reveal (see discussion of H3), green resistance towards biotechnology applications is often based on a critical attitude towards science and technological progress in general (Brossard and Nisbet 2007). And in fact, independently of the concrete biotechnology application on the political agenda, low trust in scientific experts and skepticism of the benefits of technological progress help to explain the more critical evaluation of the potential benefits of ESCR versus the potential risks of the new technology (Ho et al. 2008). Science and technology studies also point to the fact that attitudes change over time, initial negative evaluations or resistance can fade over time as the benefits of new technology become more evident or the science better and more widely understood (Nisbet 2005). Hence, we propose to test a fifth and last hypothesis:

**H5**: The more positive public opinion evaluates scientific progress, the more likely are policies without any severe restrictions.

**DATA AND METHODS**

In this section, we first present our dependent variable, the policy decisions on ESCR, and then discuss the independent variables and the Fs/QCA methodology. Due to length-constrain, all the
detailed information regarding the coding, the Fs/QCA calibration and data sources is provided in the appendix.5

THE DIVERGING PATHS IN REGULATING EMBRYONIC STEM CELL RESEARCH ACROSS 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 have been made on ESCR in these countries since the first successful derivation of embryonic stem cells in 1998.6 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: First, different types of embryo can be used for ESCR. Permissive regulation allows for creating embryos for research-purpose while restrictive policies only allow for research on imported stem cell lines from other countries. The grounds for research are the second regulatory component. Permissive regulations do not constrain research to specific grounds whereas restrictive ones ban research with the exception of a limited number of therapeutic and observational research. Finally, permissive regulatory frameworks require a general authorization for being allowed to conduct ESCR, but do not impose an approval procedure specific to each research project as restrictive regulatory frameworks require.

We have coded the policies according to an additive index of the three regulatory components (equal weighting). The calibrated into fuzzy-set scores goes from 0 (ban), 0.33 (restrictive regulation), 0.67 (intermediate regulation) to 1 (permissive regulation), see the appendix for the
detailed presentation. Figure 1 plots the regulatory trajectories for ESCR from 1998 to 2011 across Western Europe.

*Figure 1: Regulatory divergences on ESCR across Western Europe*

There is a clear pattern of policy diffusion. All Western European countries but two – Austria and Ireland – have designed policies to address regulatory issues in the field of ESCR over the last 15 years. Nevertheless, across Western Europe, the policy diffusion has not resulted in convergence towards a generally permissive regulation. On the contrary, confronted with rapid and cutting-edge developments in human biotechnology, governments have adopted strongly diverging policies, ranging from fully prohibiting ESCR to broad permissiveness. In addition, most countries have not radically changed their policy over time. Three clusters of countries can be distinguished. The United Kingdom, Belgium, Iceland, and Sweden form the *permissive cluster*. All these countries have adopted very permissive policies that allow for the creation of embryos for research purposes under the condition of a general permit to conduct ESCR granted to the research team or the research center. The *restrictive cluster* covers the countries that have imposed a general ban on ESCR or severe restrictions. In Italy, the current legislation explicitly bans embryo research and does not allow for any exception, even for non-harmful research. Switzerland and Norway initially banned ESCR and then later moved towards a less restrictive regulation and adopted a regulation similar to Spain, France, Denmark and Germany, whereby the creation of embryos for research purposes is banned, and severe restrictions are imposed on the use of leftover or imported embryos for ESCR, which has to be systematically approved. Finally, the third cluster of countries has adopted an *intermediate* approach. Finland, Greece and Portugal have banned the creation of embryos solely for research purposes, but do not impose severe restrictions on the use of leftover embryos. The Netherlands constitutes a particular case -
although the 2002 Embryo Act allowed for the creation of embryos, in 2007, a temporary ban was imposed that remains in force.

ACCOUNTING FOR THE DIVERGING PARTHES

Accounting for this divergence in a systematic way poses two main methodological challenges: first, the number of policies is limited and the size of the N (=22) does not allow for robust regression analysis; second, the literature emphasizes different explanations and this suggests that the analysis should move beyond monocausality and instead investigate the patterns in the configurational impact of different combinations of factors that may lead to a similar outcome. To this end, we draw on configurational comparative methods, and in particular Fuzzy-set Qualitative Comparative Analysis (FsQCA), which is increasingly used in comparative public policy research (for a review, see Rihoux 2012). Configurational comparative methods allows for simultaneously benefitting from the complexity of each case, while helping to identify causal processes that could lead to middle-range generalization (Ragin 2000, 2008). Before describing the FsQCA procedure applied to this analysis, we first discuss the explanatory variables. Due to words-constraint, can only describe the general principles of operationalization and refer for details to the methodological appendix.

To test the first of the two hypotheses addressing the importance of party politics, we have operationalized the causal condition “importance of the religious cleavage” as the strength of the religious parties in the party system. In most systems, religious parties are, most of the time, not strong enough to access government but can still impact on the policy making process in the Parliament (Green-Pedersen 2007). Accordingly, to fully capture any potential effect of Christian Democrats politics, instead of measuring whether Christian Democrats are in government, we use the total percentage of parliamentary seats held by the Christian Democrats and the other religious parties. The second party politics hypothesis assuming an impact of a left-wing
executive is captured through the total percentage of cabinet positions held by the Social Democrats and other left-wing parties.

Turning to public opinion-based explanations, the importance of religious values within the society is measured by the classic survey question measuring the moral attitude towards the justifiability of abortion together with the aggregate level of religiosity of the society. The public’s opinion on science is captured through the public’s attitude on scientific advances. Finally, 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 (Varone et al. 2006: 319-20). ART techniques are permissively regulated (score 3) 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 2) if some light restrictions are imposed. ART techniques are restrictively regulated (score 1) if their use is severely constrained. Finally, they could be outright banned (score 0).

The Fs/QCA procedure applied in this analysis implies two steps: the construction of the truth table and the analysis in itself. The first step consists in constructing the so-called truth table, mapping out the logically possible combinations of conditions, that is, the multidimensional vector space encompassing all the combinations among the different fuzzy-sets. In this analysis, six conditions are included, so the vector space has 64 corners ($2^6$), meaning that there are 64 logically possible combinations of conditions.

[Table 1: Truth table for positive outcomes]

The truth table (Table 1) presents the distribution of the membership scores across the 22 empirical cases – the entire set of policies on ESCR adopted in Western Europe. The empirical cases included in our analysis cover for only 14 of 64 logically possible combinations (rows 1 to 14). The 50 other combinations (rows 15 to 64) are called “logical remainders” in FsQCA
terminology. There are logically possible combinations not supported by any of the empirical cases. Once the truth table is constructed, the empirical relevance of the causal configurations must be assessed according to the number of cases with fuzzy-set memberships greater than 0.5 (column “N”) that each configuration of causes displays and then by the level of consistency (column “consistency”), that is, the degree to which a causal combination of condition is a subset of the outcome. As we aim to analyze permissive and restrictive policies, the classification of configurations will be explained when presenting the results for the two outcomes. The second step of the FsQCA procedure analyzes the truth table and reduces the logical complexity. Drawing on the Quine-McClusky algorithm (Ragin 2008), the aim of the second step is to identify the sufficient path(s) leading to the outcome (here, permissive policies) and to the negation of the outcome (here, restrictive policies).

**EXPLAINING THE DIVERGING REGULATORY PATHS OVER ESCR**

Table 2 presents the results of the minimization of the causal conditions leading to permissive and restrictive policies on ESCR. The N being relatively small, a frequency cut-off of 1 was adopted and every configuration has been taken into account in the analysis of the permissive regulatory paths. To compensate, a consistency value of 1.00 was set as benchmark criteria to distinguish between positive and negative outcomes in our 22 empirical cases. The FsQCA minimization procedure computes at least two different solutions. The parsimonious solution includes both the empirical cases and the logical remainders, while the complex solution is computed on the basis of the empirical cases only. As our N is relatively small, the complex solution based on the empirical cases displays more robust results and we will concentrate the discussion of the findings on this solution exclusively.

The complex solution reveals that four different paths result into permissive policies. As the paths display a great deal of similarity in the causal combinations, we focus the discussion on our series of three competing explanations. The major finding resulting from the analysis of the causal
configuration triggering permissive policies is the strong and systematic effect of the value-based path-dependence of the ART regulation over ESCR policies. This holds true for both the parsimonious and the complex solutions. Indeed, the causal condition PATH_ART is systematically present in all the five paths leading to permissive outcomes and across very different national contexts. If the religious factors are included in the different paths, they nevertheless do not tend to prove decisive. Indeed, a high or low level of religiosity ("church" condition), the presence or absence of religious parties in parliament ("religious") or a public opinion more or less conservative towards abortion ("abortion") all do not modify the systematic impact of value-based path dependence on the outcome of permissive regulations for ESCR. Even in societies still strongly attached to religious norms, such as Portugal and Greece, the very permissive regulation of the ART sector has strongly impacted the way these two countries have approached the regulation of embryo research. The same holds true for the ‘Social democratic politics’ explanation ("left") and the public’s attitude towards science ("science"). While leftist governments have enacted permissive policies, as is the case in Belgium and the United Kingdom, in the Netherlands a coalition government has followed the same regulatory path.

[Table 2: Sufficient paths towards permissive and restrictive policies]

Due to space-related constraints, we cannot develop the qualitative explanation for all the cases with permissive outcomes and have to focus instead on one empirical case in order to illustrate our main finding on the importance of value-based path dependence. In the Netherlands, ART treatments has benefited from strong public support since the beginning of the 1980s and the number of ART centers has increased rapidly (Timmermans and Scholten 2006; Timmermans 2007). During the 1980s and 90s, the government refrained from any restrictive intervention in the field of ART and instead only issued procedural decrees. When the technological breakthroughs in embryo-related research during the 1990s put the issue back on the political
agenda, the large coalition government adopted a similar regulatory approach. The resulting 2002 Embryo Act is one of the most permissive regulations in Europe regarding embryo-related research. While it imposes a temporary ban on embryo creation for research purposes and therapeutic cloning, the Act provides the science community with a great deal of autonomy in conducting research on embryonic stem cells derived from leftover IVF embryos. The reintegration of Christian Democrats in the government coalition in 2002 has not resulted in any major revision of the initial regulation (Timmermans 2007).

The analysis of the restrictive regulatory paths in the field of ESCR across Western Europe largely confirms our main findings for permissive outcomes. For the minimization of the configuration of conditions leading to restrictive policies, as before, the frequency cut-off is set to 1 and the consistency cut-off to 0.88. Here again, the systematic effect of value-based path dependence is striking. Both the parsimonious and complex solutions stress the importance of the absence of a permissive ART regulation to account for restrictive ESCR policies, the negated condition “path_art” being present in all the restrictive paths. Nevertheless, the restrictive regulatory paths allows for a more fine-grained understanding of the contribution of religious factors to human biotechnology policies. Among the countries that have adopted restrictive regulations, Christian Democrats and more generally, religious-based parties, have been traditionally weak in France and Denmark while they have been stronger in Germany, Switzerland, Italy and also in Norway. In Norway, the Christian Democrats were not institutionally strong enough to exert any decisive impact on the regulation and that is why this condition is absent of the path. On the contrary, in Germany and Switzerland, Christian Democrats have successfully made pressure for restricting embryo-related research more severely than ART in general. The German and Swiss cases are both characterized by an early and broad mobilization against ART and biotechnology more generally (see Rothmayr and Serdült 2004; Rothmayr and Ramjoué 2004; Engeli and Varone 2011). In neither case did the debate focus on
whether to adopt intermediary or restrictive solutions, but on whether it would not be preferable to outright prohibit ART treatments. The German case illustrates particularly well the interaction of value based path-dependence and religious factors.

The *German* Embryo Protection law was adopted in 1992 under a coalition government of Christian-Democrats (CDU/CSU) and Liberals (FDP). Based on the 1975 decision of the German Federal Constitutional Court (Bundesverfassungsgericht) to strike down the abortion law, the Christian-Democrats advocated for strong protection of the embryo. Furthermore, mobilisation against ART was also motivated by distrust of the scientific and political elite that characterized the strong German social movements of the 1980s. Against this constellation of actors seeking very restrictive policies, the German Research Council, together with other research interests, did not succeed in defending their position that embryo research should be permitted under certain conditions based on the constitutionally guaranteed freedom of science. They were somewhat more successful with ESCR in the late 1990s because they had a strong ally in Chancellor Schröder. The derivation of stem cells in Germany would have demanded a change of the existing legal framework, but the governing Social Democrats and Greens were divided over the issue, and so were the other parties. Hence, Parliament struck a compromise between the advocates of ESCR and their opponents. Parliament did not revise the 1992 Embryo Protection law, but allowed only for the *import* of stem cell lines from abroad under specific conditions.

**CONCLUSION**

All but two West European countries have designed ESCR regulations since 1998. Nevertheless policy diffusion has not resulted in any major convergence of policies throughout Western Europe (Knill 2005). Our empirical analysis confirms that domestic factors do matter. Domestic constraints and opportunities still exert a strong impact on how the policies are fostered even as
biotechnology is becoming a key field of economic competition. Because human biotechnology also touches upon moral and social norms, economic competition and technological development are not the principal driver of policy change. The domestic arena still plays an important role, and regulatory paths in ESCR across Western Europe are still diverging against all odds.

Through Fuzzy-set Qualitative Comparative Analysis (FsQCA) we were able to analyze how different, competing explanations jointly cause diverging regulatory paths. The results show that no one single regulatory path leads to permissive or restrictive frameworks for ESCR, but in any of these trajectories, whether in the secular or the religious world (Engeli et al. 2012b), earlier policies on ART are an indispensable explanation. Prior research suggested that path-dependent mechanisms were at work. For the first time, this hypothesis has been tested in a systematic manner for Western Europe. And indeed, the results of the analysis highlight the importance of prior policies regulating assisted reproduction for later adopted regulations for ESCR. Value-driven path dependency is at work, and while breakthroughs in IVF were a necessary but not sufficient condition for breakthroughs in ESCR, the reasons for a path-dependent effect are not of technical nature, but essentially political, the result of lock-in effects related to the considerable costs of debating ‘moral’ policy issues and because of the comparative advantage existing norms give to the defenders of the status quo. In short, on the one hand, our analysis confirms the findings of Banchoff (2005). But, on the other hand, they also reveal the importance of the moral dimension of ESCR policies, by pointing to the influence of religious cleavages in party systems, as well as the public’s religious attitudes. There again, our findings align with results of prior research, by Fink (2008) emphasising religious values, and more recently by Engeli et al. (2012b) on the importance of religious cleavages in party systems. However, in contrast to these prior studies, through the systematic comparison of 22 regulatory frameworks over 13 years, we were able to show the configurational impact of different combinations of factors that may lead to a similar outcome. The Fuzzy-set Qualitative Comparative Analysis (FsQCA) allowed to combine
‘a-historical and historical modes of inquiry’ and to take into account structure and agency in explaining patterns of change through including past policies and partisan cleavages as fairly stable factors together with others, more variable over time such as public opinion and party strength (Capano and Howlett 2009: 2-3).

The principal purpose of this article is to discuss why there has been no convergence for ECSR. However, one might ask to what extent the explanatory factors we evoked were also responsible for assisted reproductive technology policies in the first place. Economic and research competition do not play the same important role for regulating ART in general, than they do for ECRS. Hence, for ART policies, there is no expectation of convergence in the literature. As we pointed out in the introduction and the theoretical framework, we find various competing explanations in past research. Indirectly, our results confirm the importance of religious cleavages structuring party systems and public opinion. At the same time, because there are various paths leading to permissive or restrictive policies, clearly these factors alone are not sufficient to explain policy outcomes. This explains, at least partly, why case study based research has resulted in competing explanations, because indeed, in function of the countries studied a different combination of factors accounts for policy outcomes.

Finally, the interpretation of our results should not be understood as an argument that ESCR regulation will not change fundamentally in the near or long future, and policy stability and incremental changes will continue to dominate regulatory paths. As we well know from the policy process literature in general, and agenda-setting literature more specifically, patterns of stability and change can alter dramatically in very short periods of time. While we think it is rather unlikely that convergence will result from the adoption of new international norms, tangible results or new breakthroughs, could contribute to trigger more fundamental change that might lead to converging patterns of regulation, under the condition that domestic actors in
countries with restrictive policies mobilize in order to seize this opportunity for challenging the status quo.

1 We would like to thank Donley Studlar, Christoph Knill, Frédéric Varone and the three anonymous reviewers for their helpful suggestions and comments.

2 Embryonic stem cells are capable of self-renewal and differentiation into various types of cells. For the time being, the derivation of embryonic stem cells implies the destruction of the embryo.


4 The literature cited points towards the importance of the presence and strengths of Green parties for biomedical policies. However, Green parties are only present in some countries and we therefore have captured the influence of the Green movement in Europe by including the cleavage over science-nature in the following section on public opinion.

5 See appendix at http://www.mwpweb.eu/IsabelleEngeli/ or http://pol.umontreal.ca/repertoire-departement/vue/rothmayr-allison-christine/

6 We have excluded two major European countries – Austria and Ireland. In these countries, no binding and explicit regulations on ESCR have been elaborated so far. See the appendix for a detailed justification (see footnote 5).

7 The software fs/QCA 2.0 has been used for the analysis, C. C. Ragin, K. A. Drass, and S. Davey (2006). Fuzzy-Set/Qualitative Comparative Analysis 2.0. Tucson, AZ: Department of Sociology, University of Arizona. The description of the procedure is based on Ragin (2000, 2006).

8 See footnote 6.

9 Formula (Ragin, 2006b: 7): Consistency ($X_i \leq Y_i$) = $\sum \min (X_i, Y_i) / \sum (X_i)$, “where ‘min’ indicates the selection of the lower of the two values, $X_i$ represents membership scores in a combination of conditions, and $Y_i$ represents membership scores in the outcome”.

10 Where the negated outcome is: $\neg O= 1-O$. 

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Banchoff’s (2005) and Fink’s (2008) work explain ECRS respectively embryo research policies and not policies for assisted reproduction.
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National Science Board, *Science and Engineering Indicators 2012*,


**Figure 1: Regulatory divergences on ESCR across Western Europe**
**Table 1: Truth Table for Positive Outcomes**

<table>
<thead>
<tr>
<th>Causal Conditions</th>
<th>Outcome</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Religious</td>
<td>Left</td>
<td>Abortion</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
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<td>1</td>
<td>0</td>
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<tr>
<td>0</td>
<td>1</td>
<td>1</td>
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<tr>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
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<td>0</td>
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<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
**TABLE 2: SUFFICIENT PATHS TOWARDS PERMISSIVE AND RESTRICTIVE POLICIES**

<table>
<thead>
<tr>
<th>Paths</th>
<th>Consistency</th>
<th>Coverage</th>
<th>N</th>
<th>Case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PERMISSIVE POLICIES: PARSIMONIOUS SOLUTION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>path_art</td>
<td>0.81</td>
<td>0.93</td>
<td>11</td>
<td>All cases containing at least path_art</td>
</tr>
<tr>
<td><strong>PERMISSIVE POLICIES: COMPLEX SOLUTION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>church<em>science</em>path_art<em>left</em></td>
<td>1.00</td>
<td>0.28</td>
<td>2</td>
<td>Sweden 2005; Finland 2008</td>
</tr>
<tr>
<td>CHURCH<em>ABORTION</em>science<em>religious</em>path_art</td>
<td>0.87</td>
<td>0.38</td>
<td>3</td>
<td>Portugal 2006; Greece 2002; Greece 2005</td>
</tr>
<tr>
<td>church<em>left</em>religious*path_art</td>
<td>1.00</td>
<td>0.35</td>
<td>4</td>
<td>Belgium 2003; United Kingdom 2001; United Kingdom 2008; Iceland 2008</td>
</tr>
<tr>
<td>church<em>abortion</em>left<em>religious</em>path_art</td>
<td>1.00</td>
<td>0.14</td>
<td>2</td>
<td>Netherlands 2002; Netherlands 2007</td>
</tr>
<tr>
<td><strong>RESTRICTIVE POLICIES: PARSIMONIOUS SOLUTION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>path_art</td>
<td>0.89</td>
<td>0.74</td>
<td>11</td>
<td>All cases containing path_art</td>
</tr>
<tr>
<td><strong>RESTRICTIVE POLICIES: COMPLEX SOLUTION</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>church<em>abortion</em>path_art*science</td>
<td>1.00</td>
<td>0.37</td>
<td>6</td>
<td>France 2004; Denmark 2003; Norway 2007; Spain 2006; Norway 2003; Norway 2000</td>
</tr>
<tr>
<td>CHURCH<em>ABORTION</em>path_art<em>left</em>religious*science</td>
<td>1.00</td>
<td>0.14</td>
<td>2</td>
<td>Italy 2004; Spain 2003</td>
</tr>
<tr>
<td>CHURCH<em>ABORTION</em>path_art<em>LEFT</em>RELIGIOUS*science</td>
<td>1.00</td>
<td>0.05</td>
<td>1</td>
<td>Germany 2002</td>
</tr>
<tr>
<td>church<em>abortion</em>path_art<em>left</em>RELIGIOUS*science</td>
<td>1.00</td>
<td>0.11</td>
<td>2</td>
<td>Switzerland 1998; Switzerland 2003</td>
</tr>
</tbody>
</table>

Restrictive solutions: Frequency cut-off: 1.00, Consistency cut-off: 1.00 --- Solution coverage: 0.62, Solution consistency: 1.00
Permissive solutions: Frequency cut-off: 1.00, Consistency cut-off: 0.88 --- Solution coverage: 0.70, Solution consistency: 0.93
DIVERGING AGAINST ALL ODDS? REGULATORY PATHS IN EMBRYONIC STEM CELL RESEARCH ACROSS WESTERN EUROPE --- APPENDIX: FS/QCA CALIBRATION

Isabelle Engeli, University of Ottawa and Christine Rothmayr Allison, Université de Montréal

APPENDIX: FS/QCA CALIBRATION

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

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 have been made on ESCR in these countries. Accordingly, we have excluded two major European countries – Austria and Ireland. In these countries, no binding and explicit regulations on ESCR have 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 Austrians Bioethics Commission, March 2009, [http://www.bka.gv.at/](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 cases.

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. 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. Finally, restrictive policies ban the use of embryos and only allow research conducted on imported stem cell lines.

**Indicator 2:** Second, regarding the grounds for research, permissive regulations do not constrain research to specific grounds, whereas restrictive ones ban research with the exception of a limited number of therapeutic ground research. Intermediate regulation spells out a series of permitted grounds in an explicit way.
**Indicator 3:** Third, permissive regulatory frameworks require a general authorization for being allowed to conduct ESCR, but do not impose an approval procedure specific to each research project as restrictive regulatory frameworks require.

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

<table>
<thead>
<tr>
<th>INDICATORS</th>
<th>PERMISSIVE SCORE=3</th>
<th>INTERMEDIATE SCORE=2</th>
<th>RESTRICTIVE SCORE=1</th>
<th>BAN SCORE=0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EMBRYO TYPE</strong></td>
<td>Creation of embryo</td>
<td>Leftover embryo</td>
<td>Imported stem cell lines</td>
<td>Ban</td>
</tr>
<tr>
<td><strong>GROUNDS</strong></td>
<td>General permission</td>
<td>Explicit mention of specific grounds</td>
<td>Therapeutic grounds only</td>
<td>Ban</td>
</tr>
<tr>
<td><strong>PROCEDURE</strong></td>
<td>General approval procedure</td>
<td>Specific approval procedure for each type of research</td>
<td>Specific approval procedure for each research project</td>
<td>Ban</td>
</tr>
</tbody>
</table>

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 member 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 definition of religious parties. 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

<table>
<thead>
<tr>
<th>% Parliamentary Seats</th>
<th>Fuzzy-set Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% to 10%</td>
<td>0</td>
</tr>
<tr>
<td>10% to 15%</td>
<td>0.33</td>
</tr>
<tr>
<td>15.1% to 20%</td>
<td>0.67</td>
</tr>
<tr>
<td>20.1% to 36.6%</td>
<td>1</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>% CABINET POSITION</th>
<th>FUZZY-SET SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 %</td>
<td>0 “not in power”</td>
</tr>
<tr>
<td>22.25% to 32.16%</td>
<td>0.33 “minor coalition member”</td>
</tr>
<tr>
<td>50% to 79.18%</td>
<td>0.67 “major coalition member”</td>
</tr>
<tr>
<td>100%</td>
<td>1 “in full power”</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>% OF RESPONDENTS CONSIDERING ABORTION AS “NEVER JUSTIFIABLE”</th>
<th>FUZZY-SET SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2 % to 18.8%</td>
<td>0 “permissive attitude toward embryo”</td>
</tr>
<tr>
<td>18.9% to 29.8%</td>
<td>0.33 “rather permissive attitude toward embryo”</td>
</tr>
<tr>
<td>29.9% to 40.7%</td>
<td>0.67 “rather conservative attitude toward embryo”</td>
</tr>
<tr>
<td>40.8% to 51.6%</td>
<td>1 “conservative attitude toward embryo”</td>
</tr>
</tbody>
</table>

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) 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 A5: CALIBRATION OF THE “CHURCH ATTENDANCE” CONDITION**
### Table A6: Calibration of the “Attitude Toward Science Advance” Condition

<table>
<thead>
<tr>
<th>% of Respondents considering science advance as “helpful for mankind”</th>
<th>Fuzzy-set score</th>
</tr>
</thead>
<tbody>
<tr>
<td>33.8% to 42.5%</td>
<td>0 “mistrusting attitude toward science advance”</td>
</tr>
<tr>
<td>42.3% to 50.7%</td>
<td>0.2 “rather mistrusting attitude toward science advance”</td>
</tr>
<tr>
<td>50.8% to 59.2%</td>
<td>0.4 “rather mistrusting attitude toward science advance”</td>
</tr>
<tr>
<td>59.2% to 67.6%</td>
<td>0.6 “rather trusting attitude toward science advance”</td>
</tr>
<tr>
<td>67.7% to 76.1%</td>
<td>0.8 “rather trusting attitude toward science advance”</td>
</tr>
<tr>
<td>76.2% to 84.5%</td>
<td>1 “trusting attitude toward science advance”</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>PERMISSIVE</th>
<th>INTERMEDIATE</th>
<th>RESTRICTIVE</th>
<th>BAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORE: 1</td>
<td>SCORE: 0.67</td>
<td>SCORE: 0.33</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>Italy</td>
<td>Denmark</td>
<td>Germany</td>
</tr>
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<td>Finland</td>
<td>Spain06</td>
<td>France</td>
<td>Norway00</td>
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<tr>
<td>Greece05</td>
<td>Netherlands02</td>
<td>Spain03</td>
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<tr>
<td>United Kingdom 08</td>
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</table>

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