Abstract The gap between the demand and supply of organs for transplantation is a worldwide phenomenon that continues to tax policy-makers. We consider recent policy reforms in Germany, drawing on evidence from Spain and Austria for comparison. Our analysis adopts Kingdon’s multiple streams model which suggests that windows of opportunity for policy change open when an issue of public concern combines with a plausible solution and favorable political circumstances. Evidence is central to this process, but the type of evidence and the ways it is used, differ from technocratic formulations of evidence based policy-making. Scientific evidence may contribute to the rational appraisal of options, but this and other forms of evidence are also used rhetorically to generate political will and public support for change. We conclude by considering what the formation of organ donation policy in Germany reveals about the processes of policy-making under the competing imperatives of rationalism and democracy.

Keywords Organ Donation, Health Policy, Multiple Streams Model, Germany, Austria, Spain

1. Introduction

In August 2010, Frank-Walter Steinmeier, leader of the opposition SPD in the Bundestag, (the German parliament), donated a kidney to his sick wife [1]. The incident was widely reported in the media, drawing attention to the long-standing problem of inadequate supply of organs for transplantation and the 12,000 Germans then waiting for transplant surgery [2]. The Steinmeier donation sparked a national debate about organ donation policy, which coincided with a European Commission action plan on organ donation and transplantation that combined greater cooperation between member states with a requirement for national policy reform, [3], including a deadline for the reform of member states’ national transplantation laws by summer 2012. Steinmeier himself played a central role in formulating the policy response and garnering cross-party support for reform. The cross-party bill to amend the 1997 Transplantation Act was enacted in May 2012, but this apparent consensus masks a debate that was contentious and highly rhetorical. Rather than a triumph for evidence based policy-making, many expert commentators have criticized the resulting compromise and questioned the efficacy of the new measures.

2. Objectives

Our aim is to present a policy analysis of the above events using Kingdon’s multiple streams approach, [4], in order to reveal the factors and processes that shaped the current uneasy consensus among policy-makers, focusing particularly on the different forms of ‘evidence’ The main focus is on the German context, but evidence from Spain and Austria is also drawn upon for comparative purposes.

3. Methods: The Multiple Streams Approach to Policy Analysis

The multiple streams approach to policy analysis was developed by John Kingdon and presented in his book Agendas, Alternatives and Public Policies, first published in 1984 and now in its second edition, [4]. Central to the approach is the claim that policy emerges through interaction between three relatively independent processes or ‘streams’. The problem stream refers to the process by which issues are articulated and placed on the decision-making agenda. Not all legitimate concerns become defined as problems and may not be recognized as such unless a viable policy solution is available. The policy stream refers to proposals for change. The policy process requires clearly articulated plans for action from which politicians and policy-makers can select a solution. The politics stream describes the actions of political stakeholders and institutions, for example, the actions of pressure groups, shifts in public opinion and the electoral cycle. Policy change is likely to occur when there is a conjunctures between the three streams, that is, when recognizable problems coincide with feasible solutions and a favorable political climate. At such times a policy window
opens allowing policy change to occur, and policy entrepreneurs (people who favor a particular solution) become active in the problem and policy streams, jockeying to promote their favored solution. However, the policy window may not stay open for long and if the opportunity is missed then policy entrepreneurs may have a lengthy wait before policy change becomes viable again.

Politicians, academics, civil servants, lobbyists or even private citizens can all act as policy entrepreneurs, but must have certain attributes, skills or resources in order to influence policy. Kingdon lists three: the right to be heard — either because they represent others, have specialist expertise, or have decision-making power; political connections and know-how; and finally what Kingdon describes as the most important quality, the persistence required to push their ideas in different fora. The multiple streams approach has been applied to many different aspects of policy making in the health domain, [5-9].

Kingdon’s model provided the theoretical framework for our study, however, we adopted a case study design to inform the collection of data. Following Yin [10] our method is an historical case study comprising collection and analysis of primary and secondary document sources including: legal documents, systematic reviews, articles in scientific journals, political magazines and newspapers, books, reports and statistical data. The literature search comprised searches of Web of Knowledge, Pubmed/Medline, and Mendeley, and governmental and stakeholder websites were also accessed. Primary information was provided by Deutsche Stiftung Organtransplantation (DSO) in Germany and Gesundheit Österreich GmbH (GOEG) in Austria in reply to a list of questions about their policies, activities and waiting lists, submitted by one of the authors (A-CH). The documentary evidence was used to assess the socio-political and institutional context leading to enactment of the German transplantation legislation in May 2012 [11, 12].

4. Results

Our findings are presented in three sections which correspond with the three streams of Kingdon’s model.

4.1. The Problem Stream

Kingdon [4] lists three factors that can bring a potential problem to the attention of policymakers: a negative change in an indicator; feedback from the operation of a program; and a focusing event, which may include catastrophes, crises, or the personal experience of a policymaker which may have symbolic significance as well as practical consequences.

Each of these factors can be identified in the problem stream relating to transplantation policy in Germany. As Kingdon [4(p.93)] explains, ‘it helps for a problem to be countable, since people find numbers easier to understand than a complex puzzle of causes and effects’, and the availability of compelling statistical evidence has played a major role in forming and shaping the problem of organ donation. One of the more powerful indicators is the mortality rate among people waiting for an organ transplant. At the time of the Steinmeier donation in August 2010 the media were reporting that 12,000 Germans were on the waiting list for a transplant. Waiting times for a kidney transplant can be up to six years [13] although waiting times for heart, liver and lung transplants are shorter. In 2010, 4,205 organ transplantations from 1,296 deceased donors and another 878 from living donors were conducted [14].

With 7,029 people newly registered on the waiting list, the need for organs and demand for transplants increased faster than the organ supply and transplantation capacity. As a consequence, many patients die while waiting for an organ to become available, giving rise to the often cited statistic that every day three Germans die while waiting for transplant surgery [15, 16].

Technological and clinical advances may have an autonomous impact on the generation of public issues, but as Kingdon suggests, it is often the activities of policy entrepreneurs that mediate the connection between the two. Thus, the above indicators serve not just as a measure of ‘the degree of shortage’[4(p.91)], but also provide the raw material from which policy entrepreneurs can construct a particular reading of the problem. Kingdon [49p.93]) suggests that ‘constructing an indicator and getting others to agree to its worth become major preoccupations of those pressing for policy change’. Policy entrepreneurs invest time, energy and other resources to transform indicators into a recognized problem. For example, commentators in the media and in government have used the claim that ‘every day three people die in Germany because they wait in vain for an organ donation’ [13, 17] to construct the problem in a particular form and invest it with a potent emotional and moral imperative.

Through this emotive use of indicators non-donation is transformed into the cause of death, rather than cardiac or renal failure, or other clinical or organizational factors. Moreover, it implicitly suggests that those who receive an organ will be ‘rescued’ [18], and that there are no other significant obstacles on the pathway between the decision to donate and the rescue of the patient. Presenting the problem in terms of low donation rates pre-figures the solution of encouraging or compelling more people to register their intention to donate their organs and to carry a donor card. Concern was expressed in the media after the number of organ donors dropped in 2008 and 2009 compared to the steady increases until 2007, fuelling a minor moral panic that the German people were becoming more reluctant to donate their organs. It is regarded as a paradox that while about three
quarters of the population supports organ donation, less than a quarter have documented their willingness to become a donor on a donor card [19, 20]. The implication is that support for organ donation has not been translated into actual donation because of the apathy or inertia of potential donors. The donor card enables carriers to give explicit consent and active support, although it also contains the options of dissent and of delegating the decision to others. However, symbolically it has been invested with moral meaning. To carry a donor-card is to express altruism and reciprocity and the wish to spare family members the burden of decision, while reluctance to do so signifies an unwillingness to take a decision and refusal to think about death [20]. What might be construed simply as a personal choice, therefore takes on a moral significance as an indicator of a national decline in social solidarity or civic mindedness. This perception has been fueled by comparison with other European countries.

Comparisons with Spain and Austria have figured prominently in the public discourse on organ donation and transplantation in Germany [21, 22], often focusing on the donation and transplantation rates and the numbers of people waiting for transplant surgery, but also considering the different policies that prevail in each country. International comparisons are complicated by the fact that different agencies define and count donation, transplantation and waiting lists in different ways and the reliability of the data can sometimes be questioned. This has often confused the public debate. For the purposes of consistency we use the following indicators and definitions which are broadly supported by the academic literature [23-25]:

Actual donor rate: The number of eligible donors transferred to the operating theatre from which at least one solid organ has been removed, irrespective of whether these organs were transplanted or not per million population (pmp) in the respective country.

Utilized donor rate: The number of donors from whom at least one solid organ has been removed and transplanted, pmp in the respective country.

Transplantation rate: The number of transplantation procedures, i.e. the number of recipients of donated solid post-mortem organs pmp in the respective country.

Waiting for transplant rate: The number of patients waiting for transplant surgery at a given point in time, pmp in the respective country.

Spain leads the international league with an actual donor rate of 35 pmp and a transplantation rate of 104 pmp. When the national Spanish transplantation organization ONT was founded in 1989, the country occupied a ‘mid-low position’ amongst the European countries, similar to Germany now. It continuously improved its post-mortem donor rate and became a model for the European Union [26]. Spain, therefore, serves as an example of what might be achieved in Germany, as well as demonstrating how far behind the Germans are – a perception sharpened by a tendency in the research literature to compare the actual donor rate for Spain, (35 pmp in 2011) rather than the utilized donor rate (31 pmp in 2011), [24].

The donation rates for Austria lie between those of Spain and Germany, with a utilized donor rate of 23 pmp, and a transplantation rate of 90 pmp in 2011. However, as Germany’s neighbor in the South shares a common language and similar culture, unfavorable comparisons have a particular resonance in Germany. Data for 2011 show that the number of people waiting for a transplant was proportionately lower than the number in Germany, 118 PMP and 141 pmp respectively. Although both countries fail to meet their transplant needs, the shortage is larger in Germany and waiting times shorter in Austria [27]. As Kingdon has observed in the US, cross-national comparisons are often exploited to draw attention to a problem: ‘The mere fact of being behind in ‘the greatest country on earth’ is enough to constitute a problem for some people’ [4 (p.111)]. Germany’s poor performance compared with Spain and Austria on key organ donation indicators, appears to pose a similar threat to national pride. In the hands of policy entrepreneurs, these comparative indicators can be made to symbolize a national malaise or declining social solidarity, posing the question of why the German people appear less willing than their European partners to transform their broad support for organ transplantation into a personal decision to donate. The question is particularly vexed because as a member of the multi-national Eurotransplant network, Germany receives more organs from other European countries than it provides to the network, [28, 29].

The above themes have been circulating in the problem stream for several years, (and the vehement debates around transplant legislation from 1970s and 90s remain in the minds of many Germans), but it was the Steinmeier donation that provided the focusing event that made them coalesce into a specific policy problem and propelled them up the policy making agenda. Steinmeier announced his donation in the media explaining that the waiting-time for a post-mortem kidney would be too long [30]. This ‘altruistic decision’ greatly enhanced Steinmeier’s credentials as a policy entrepreneur enabling him to speak on behalf of others affected by the shortage of donated organs, and the episode no doubt instilled in Steinmeier what Kingdon describes as the essential attribute of persistence. Through a member of the opposition party, the wave of public sympathy and concern generated by the story led to him leading the cross-party committee that drafted the policy response. Having described the problematisation of organ donation in Germany we now turn to the proposed solutions circulating in the ‘policy stream’.

4.2. The Policy Stream

The policy stream is where potential solutions are developed and Kingdon [4] claims this process is largely separate from the ‘problem’ and ‘politics’ streams. We have argued that the organ-donation policy stream is not as separate from the problem-stream as Kingdon suggests, because the way in which organ donation was problematized tended to imply presumed consent was the solution.
However, this and other policy solutions were circulating in the policy community long before the problem became apparent to decision-makers [31], contradicting the rational sequence of problem diagnosis and strategy development proposed in the stages heuristic, [32]. The narrow community of academics and professionals, the ‘hidden participants’ as Kingdon [4 (p.200)] calls them, had been busily working up proposals behind the scenes in anticipation of the policy window opening.

Events in the problem stream, (described above), tended to promote the presumed consent solution, at least in the early stages of the policy debate, leaving supporters of alternative solutions struggling to influence the policy-makers. Below we consider the main policy options and the struggle between policy entrepreneurs to have their favored solution adopted.

In response to the Steinmeier donation, the Head of the Christian Democrats in the German parliamentary Health Committee, Rolf Koschorrek, announced his intention to champion the opting out (or presumed consent) model in order to increase the donation rate, (quoted in [1]). Adoption of the presumed consent model would require legislative reform of the transplantation policy introduced in 1997, under which consent is dependent upon the presence of a donor-card, or, consultation with the relatives of a patient declared brain-dead as to whether the patient had previously made any declaration regarding organ donation, and failing that, whether the relatives would be willing to give proxy consent. In the case of several relatives with ‘similar ranking’ only one needs to be involved in the decision process, but each of them has a right of veto [33]. Under this system there were many ‘decision-gaps’ through which a potential organ donation could be lost. A potential donor may have been in favor of donation, but not got around to completing a card. A donor card could have been completed, but lost or not carried. Physicians may be reluctant to discuss donation with grieving relatives. Relatives may disagree among themselves, or be reluctant to take the decision to allow donation. In theory, the presumed consent model plugs many of these decision gaps, by enabling organs to be transplanted unless the potential donor has officially registered his decision to opt out. As advocates of libertarian paternalism or ‘nudge’ have indicated, such a strategy has the benefit of channeling human inertia towards a desired social outcome, while maintaining the option for dissenters to opt-out without too much difficulty, [34]. But does this work in practice?

Within Europe, 24 countries have an opting-out system with presumed-consent and 16 have an opting-in system with informed-consent [27]. Some countries like the UK and the Netherlands have considered adopting presumed consent [35, 36]. However, while presumed consent may exist de jure, what happens in practice can be quite different to the theory.

Spain introduced presumed-consent legislation in 1979 and the German mass media, (and several international scholars) have argued that this is what lies behind Spain’s high organ-donation rates, [37, 38, 35]. However, Fabre et al. [35] suggest that this claim is ‘based on the belief that presumed-consent equates with organ donation’, but ‘Spain’s outstanding deceased organ donor rate cannot reasonably be attributed to its presumed-consent laws’, as de facto, Spain practices an informed-consent policy, similar to Germany. Donor consent or dissent is documented on donor-cards, but only 8 percent of the populations possess one [35] and consent is routinely requested from the family. Similarly, in Austria, despite having presumed-consent legislation, it is the established practice to ask relatives of the potential donor for permission [39]. If relatives are routinely consulted and have a de facto right of veto then the legal presumption of consent amounts to very little.

If it is not presumed consent legislation that accounts for the higher donation rates in these countries then what is it? One factor is cultural differences that influence relatives’ willingness to give proxy consent. In Spain 81 percent of the next of kin consented in 2010. The Spanish transplantation organization (ONT) views the 19 percent that refused as a problem accounting for the ‘loss’ of 1649 potential donors with an estimated 4056 organs between 2006 and 2010 [40]. However, this compares favorably with refusal rates of 30-40 percent between 1979 and1989 [35]. This reduction has been achieved not by investing in expensive public awareness campaigns, (as the German government often has), but by the ONT developing a close relationship with the media and providing the public with regular reports [41].

Similarly, in Austria the population has a positive attitude towards post-mortem donations attributed to the long standing tradition of postmortem examinations in Austrian hospitals. However, the role of cultural factors should not be over-stated, because Germany also has high levels of public support for donation, the problem is translating this into actual donations, and organizational factors, particularly within health care institutions, may also play a role. Austria has recently introduced transplant coordinators and improved the provision and optimal realization of brain death diagnosis so that more potential donors are identified and reported. These improvements are expected to further increase Austrian post-mortem donations to meet the target of 30 pmp [27].

The comparative success of the Spanish transplantation system has also been attributed to innovative management initiatives [41]. The network of well-trained transplant coordinators plays a key role. Spanish hospitals also have ring-fenced funding for their activities in donation, transplantation and dialyses [42]. The decentralization in Spain, which Matesanz et al. consider a ‘major principle’, imposes the need to obtain regional consent for national initiatives [43], and the ONT under the leadership of Dr Rafael Matesanz may have contributed to the success in this area [44]. In 2008 ONT embarked on a strategic plan targeting a 40 pmp donation-rate [45]. The plan includes improving access to Intensive Care Units ICUs, training staff, cooperation with private hospitals, quality maintenance and new surgical techniques [40].

Proponents of presumed consent sometimes neglect the
extent to which factors like access to ICUs, attitudes of hospital staff and relatives, and organ quality, affect outcomes in the process and decision chain of organ donation [46]. The German mass media played a key role in framing the problem in terms of the unwillingness of individuals to document their consent on a donor-card, reducing a complex and multifaceted issue to a simple solution. Professional and academic sources presented more sophisticated analyses of the problem and proposed a broader range of solutions, [38], including the identification of potential post-mortem donors in hospitals, the appointment of hospital based transplantation coordinators, financial compensation for hospitals and incentives for donors. Living donor transplants, artificial organs and xenotransplantation have not been proposed as viable policy options due to their restricted application or early stage in xenotransplantation have not been proposed as viable policy options due to their restricted application or early stage in development [47]. Commercial trade of organs is illegal in Germany and the European Union and has not been put forward in the current debate despite its prospect of increasing the kidney supply and reducing organ tourism to other countries [48]. Similarly, giving registered donors priority for a transplant, should they require one in the future, as the Israeli points system does, has proven unpopular for ethical reasons [49].

As the organ donation policy debate matured in Germany during the months following the Steinmeier donation, some of the alternatives to presumed consent began to filter through. Health Minister Daniel Bahr and Gunther Kirste, Head of the German Organ Transplantation Foundation (DSO), both lobbied for the appointment of hospital based transplant coordinators [50], while others raised concerns about the ethics of presumed consent [51]. However, the factors that shaped the eventual policy compromise were not exclusively drawn from the rational principles of evidence based policy, but also from the cloudier waters of the politics stream, to which we now turn.

4.3. The Politics Stream

The political impetus to reform transplant legislation in Germany came not just from domestic policy entrepreneurs, but also from international agencies. The increasing gap between demand and supply for organ transplantations is a worldwide phenomenon, which also affects the countries with the highest donation and transplantation rates, prompting international agencies to encourage national governments to act. The World Health Organization has called for self-sufficiency in transplantation and developed guiding principles, including maximizing donation from deceased donors [52, 53]. The European council has also recognized the need for action [46,54], urging member-states to reform their legislation by August 2012 in compliance with its directive [55]. Setting a specific European deadline for policy reform provided a very clear policy window in which German political institutions could respond to domestic drivers of change, like the Steinmeier donation. European directives are not always sufficient to determine the legislative timetable for policy reform at the national level, but in this instance, the German government has met the deadline by passing legislation in May 2012.

Meeting the European deadline required compromise between different stakeholders over complex and sometimes controversial issues as well as negotiating the particular set of political institutions and processes that prevail in Germany. Our analysis suggests that these political factors shaped the policy outcome just as significantly as factors in the problem and policy streams. As our analysis of the policy stream indicates, the discussion of potential solutions focused primarily on the merits and demerits of ‘presumed consent’ (in which potential donors are assumed to have consented unless they have registered their decision to opt out), versus ‘mandated choice’ (in which the population is either obliged or strongly encouraged to register their assent or dissent to donation), versus ‘strict consent’ (in which potential donors or their relatives opt in to donation on a voluntary basis). One might expect the Christian Democrat, Social Democratic and Liberal parties to have different ideological standpoints on this issue reflecting their different beliefs regarding what the relationship between the state and the individual ought to be. In addition there are vertical and horizontal tensions between the different institutions and layers of the state, for instance between the legislature and the Supreme Court, and between the national Parliament (Bundestag) and the Federal Council (Bundesrat). Public opinion (perhaps as an indicator of future electoral support), and the lobbying of other stakeholders, some of whom were advocating alternative measures, such as funding for hospital based transplant coordinators and better access to ICUs, also influenced the decision-making process.

These political factors make for a very complex decision-making process. As Kingdon has suggested ‘this policy primeval soup does not closely resemble a rational decision-making system with few well-defined alternatives among which decision-makers choose’, [4 (p.124)], but rather a much more fluid process of negotiation and compromise, in which policy options are adapted, combined or transformed, often with scant regard to evidence of their effectiveness. Not all of this ‘horse-trading’ is done in the public eye, but some of it is, enabling us to piece together a crude account of events in the politics stream.

The German government currently comprises a coalition between the Christian-Democrats and the Liberals. Since the elections for the Bundestag in 2009 support for the Liberals has declined reducing their influence as the junior partner in the coalition. The Ministries of Health and Justice are nominally responsible for transplant policy reform, and both are currently headed by Liberals. The Liberals have traditionally opposed presumed consent, with the previous Liberal Minister of Justice, Schmitz-Jortzig voting in favor of strict donor consent and informed choice in 1997 [56]. However, in the aftermath of the Steinmeier donation, the head of the Christian-Democrats in the parliamentary health committee expressed his intention to pursue a policy of
presumed consent, suggesting a degree of disagreement between the coalition parties.

Similar tensions were in evidence at the regional level. Without consulting the federal minister, the 16 states’ ministers of health met and discussed a proposal for presumed-consent jointly produced by three of their colleagues, one Social-Democratic and two Christian-Democratic [57]. The meeting, however, agreed on ‘mandated-choice’ combined with a national register [58]. Reportedly, Christian-Democratic and Social-Democratic ‘expert-politicians’ (fachpolitiker) had been jointly collaborating for some time on such a solution’ [59].

Experts had discussed the medical, ethical and juridical aspects of a policy change in a public hearing of the health committee in June 2011. A compromise was found in late November 2011 between the federal minister and the heads of parties represented in parliament. Steinmeier, acknowledged for his ‘expertise’, played a decisive role in arranging the consensus, which proposed that the health insurance funds should be mandated to present their members with a voluntary choice of options, one of which was ‘not deciding now’, which would then be recorded on their medical certificate [60]. The funds agreed to take on this responsibility [61]. However, many stakeholders, like the association of medical students [62], remained dissatisfied with the proposed compromise. The proposal sets aside presumed consent in favor of a diluted form of mandated-choice, (in which individuals have the option of not making a choice), and did not include hospital based measures such as transplant coordinators or better access to ICUs. As late as March 2012 Steinmeier’s compromise dominated the public policy discourse and was widely expected to be the blueprint for legislation [63]. As we shall see, the actual policy that passed into legislation in May 2012 included additional measures that had not been widely mediated beforehand and which have subsequently received criticism from a number of stakeholders. Before turning to the legislation we briefly summarize the key political factors that shaped the compromise proposals:

The nature of the issue – the aim of policy-makers may have been the uncontroversial one of increasing the availability of organs for transplantation, but the fact that the public policy debate was constructed in terms of presumed consent versus different forms of opting in, had the effect of heightening political sensitivities. What might have been a presumed-consent jointly produced by three of their colleagues, one Social-Democratic and two Christian-Democratic [57]. The meeting, however, agreed on ‘mandated-choice’ combined with a national register [58]. Reportedly, Christian-Democratic and Social-Democratic ‘expert-politicians’ (fachpolitiker) had been jointly collaborating for some time on such a solution’ [59].

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The nature of the issue – the aim of policy-makers may have been the uncontroversial one of increasing the availability of organs for transplantation, but the fact that the public policy debate was constructed in terms of presumed consent versus different forms of opting in, had the effect of heightening political sensitivities. What might have been a pragmatic discussion focusing on evidence of the effectiveness of different ways of improving the organization and practice of managing donation at the hospital level, became a profound ethical dilemma about the nature of brain death and the relationship between the state and the individual. This had a number of practical consequences. As commonly occurs with ethical or moral issues, MPs were allowed to vote according to their consciences rather than being obliged to support their party’s preferred solution. Secondly, it raised the prospect of legislation being overturned by the Supreme Court. As well as distracting attention from more practical solutions, the heightened political sensitivity also eroded the political will to act decisively and opened the door to compromise.

The search for consensus - There is an established tradition of consensus seeking in post-war German politics which is amplified by the tension between national and regional government and by the exigencies of coalition politics. The issue of presumed consent tested this tendency because it evokes ideological differences about what the relationship between the state and the individual should ideally be. Even so, realpolitik requires a high degree of consensus to ensure that legislation is passed and implemented. Thus, the Steinmeier compromise offered the lowest common-denominator that all key parties could support, even though few were satisfied with it or felt that it offered the most effective solution. As Kingdon [4 (p. 103)] has observed, ‘even if it is questionable whether government officials have solved a problem, they sometimes feel that they have addressed it by passing legislation or making an administrative decision.’

Consideration of public opinion - The Steinmeier donation and other events in the problem stream stimulated a high degree of public support for policy reform to tackle the organ supply problem. However, the public debate about presumed consent, as well as raising concerns about the power of the state and personal freedom, also raised a moral concern about declining levels of altruism, personal responsibility and social solidarity. Presumed consent is a means of compensating for donor apathy and inertia which robs the potential donor of the opportunity to demonstrate their altruism and social solidarity by positively opting into the donor register. Thus, in a representative study among the German population, 41% of respondents opted for ‘mandated choice’, one third preferred the current policy, but only 23% supported ‘presumed-consent’ [64]. Over the last few decades in Germany traditional bonds between parties and voters have loosened, with the result that public opinion on particular policies can easily be transformed into shifts in electoral support. Given this degree of political volatility, politicians are unlikely to support any policy that is strongly opposed by the electorate. Moreover, the lack of public support for presumed consent also raised the prospect of a negative reaction among potential donors which might even reduce the number of donors. Brazil is often cited as a country that introduced presumed consent legislation only to have to repeal it [65].

These political factors have also influenced the two previous policy windows in Germany, each time resulting in stalled and ineffective policy-making. Whether or not presumed consent actually operates in the countries that have adopted it de jure, and whether it, rather than more practical organizational and operational measures, accounts for their higher donation rates, are moot points. But what seems clear, in the German context, is that the pursuit of presumed consent by leading policy entrepreneurs has tended to side-track the public policy debate into a principled ethical discussion about state power, personal freedom, altruism and social solidarity, which has distracted attention from
alternative solutions. In the final section we examine the policy solution that emerged from the debate.

5. Discussion: The Policy Outcome

The European Community deadline for reform of national transplant legislation fell in August 2012 [55], and the German reforms passed into legislation at the end of May 2012 in the Bundestag and mid-June in the Bundesrat. The public policy debate had been high-profile and protracted, but even so, many commentators were surprised and dissatisfied at the outcome. Despite a lengthy search for compromise, critics have argued that the new legislation was drafted in haste, poorly specified and lacked the full support of the opposition. In the online journal Spiegel one commentator claimed that “the measures for inquiring into the willingness to donate organs are insufficient, important financial issues for the hospitals are not answered and the law arouses suspicion” [66] (translated by A-CH).

The main points of the new policy are as follows, [11, 12]:

- Every insured inhabitant of Germany will receive information about organ donation plus an organ donation card (empty) from his/her mandatory or private health insurance fund and will be asked to state whether he/she wishes to become a (potential) organ donor or not, or whether he/she would like to postpone the decision. The insurance fund will regularly (probably after 2 years, then after 5 years) approach the person again. The same documents will be issued when a person applies for a driving license.
- Every hospital, which has the facilities for identifying and extracting organs, (some 1400 hospitals with intensive care units) will be expected to nominate or appoint a transplant coordinator. This is already a requirement in 8 out of the 16 German states, but current capacity is insufficient. The coordinators will need to be trained in the medical and psychological aspects of transplantation and it remains unclear how the new posts will be funded. The compensation currently paid by DSO compensates hospitals for organ extraction, but this falls considerably short of the actual costs incurred by the hospitals and the new legislation does not indicate how this will be addressed.
- Living donors will be better protected, by obliging the respective (mandatory or private) health insurance fund to cover any follow-up costs resulting from the living donation.
- The role of the DSO will be strengthened with regard to safety and quality. Although critics have argued that DSO is (and will remain) largely unregulated and unaccountable. Anonymous complaints were raised at the end of 2011 about nepotism inside DSO and one of the two heads of the organization has resigned, and the other has retired (due to age). Although the main component of the legislation, the personalized approach to asking and recording donor consent, is essentially what was proposed in the Steinmeier compromise, other elements, such as the increase in transplant coordinators came as more of a surprise, although policy entrepreneurs had lobbied for them. As Kingdon has argued, much of the fine grain of policy drafting is conducted out of the public eye by ‘hidden participants’ [4 (p.200)], including expert-politicians, professionals and bureaucrats. Given the German tradition of corporatism and the tendency to draw on external expertise from non-governmental institutions, the assumption seems legitimate that representatives of the DSO and the chamber of physicians had been involved in drafting the policy and may have influenced the decision to drop the presumed-consent model and focus on other organizational issues. As information is limited, it is difficult to judge whether the outcome resulted from bargaining in the politics-stream or persuasion in the policy-stream [4 (p. 199)]. The dual role of prominent expert-politicians obscures the analysis, yet the type of compromise arrived at suggests a predominance of bargaining rather than evidence based persuasion. Comparative evidence cannot answer whether the particular settlement reached in Germany will be sufficient to solve the organ supply problem, even if it was the most acceptable to the key stakeholders.

6. Conclusions

Time will tell whether the new measures will prove effective in increasing German donation and transplantation rates. Critics have argued that much of the new legislation was added in haste at the last moment and that it contains flaws and omissions which might derail the policy, however, there may be scope for clarification and minor revisions without the need for further legislation. Our analysis supports Kingdon’s claim that policy-making occurs when the problem, policy and politics streams converge under favorable conditions. The comparative evidence of relatively poor donation indicators in Germany, the impetus given by the Steinmeier donation, the widely recognized ‘solution’ of presumed consent, coupled with the deadline for action set by the EU directive, combined to open the policy window and drive through reform.

There are broader lessons to be learned from this exemplar about the policy-making process. Our analysis supports the critique of technocratic approaches to evidence based policy-making. Such approaches adopt an engineering approach to policy-making that emphasize objective evidence of need and a scientific approach to option appraisal and evaluation [67]. From this perspective, policy-making becomes a technocratic process in which the boundaries of legitimate knowledge are narrowly drawn and the claims and activities of political agents and professional networks are either relegated to the margins or else viewed as sources of distortion and bias. Critics have argued for a more pluralistic approach which recognizes that ‘political
know-how’ and ‘practical professional field experience’ are themselves evidence bases that complement scientific and technical analysis [68]. Our analysis shows these alternative knowledge bases being used by policy entrepreneurs and experts in the donation field to generate political will and public support for policy change. The resulting policy is based on a synthesis of scientific evidence, reason, rhetoric and political negotiation. But is this how policy-making should be? From the technocratic perspective political and professional factors are little more than ‘noise’ distorting the pure signal of scientific reason. However, science rarely offers absolute answers to policy questions, partly because the knowledge base is often incomplete, but also because the decision-making process often depends upon value judgments about the desirability of different outcomes, which in turn require political legitimacy and public support. Scientific evidence can play a vital role in debunking the unfounded claims of political rhetoric, but it can never entirely usurp the democratic process.

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