Organ Donation, policy and legislation

Chapter 8 General discussion
8.1 Introduction

In this thesis we have focused on the Dutch policy to increase the supply of post mortem donor organs, with special reference to the Organ Donation Act’s objective in this matter. Central to this is a social issue, besides the policy issues. The social issue relates to the lengthy waiting periods for patients to receive an organ. In the Netherlands approximately 1,300 people are waiting for an organ, while there are only some 200 post mortem organ donors on a yearly basis. This means there is a considerable discrepancy between the demand for donor organs and the supply of organs, resulting in waiting lists, and consequently long waiting times for patients to receive an organ; patients even die while waiting (Defever, 1990; Council of Europe, 2008; Smith, 2009). In order to reduce the gap between the supply of and demand for donor organs, and to shorten the waiting list the Dutch government has implemented a policy to increase the supply of organs. In 1998 the Dutch Organ Donation Act came into force, introducing a consent system based on explicit consent and followed by the implementation of several additional policy measures. However, in the past decade the post mortem donation rates have not increased and the gap remains. This has raised a policy issue, as was demonstrated by the ongoing debate about the ability of the Dutch policy on organ donation to increase the donor organ supply. The debate has focused on the consent system. Because countries with a presumed consent system have higher donation rates, it has been suggested that the Netherlands should change the consent system and introduce a system based on presumed consent. But will changing the consent system indeed increase the supply of donor organs? After all, changing the consent system is a radical step, and other factors may influence the outcomes of such a change. Thus further analysis is called for. Therefore, the main research question was: “What is the impact of legislation on organ donation and additional policy measures on the supply of post mortem donor organs, with special reference to the Netherlands?”

We assumed that the supply of donor organs depends largely on the impact of legislation, additional policy measures, and on external factors, such as
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the number of deceased people eligible for organ donation (e.g. deaths from traffic accidents and Cerebral Vascular Accidents (CVA)). Furthermore, legislation and policy measures are often intertwined and their effects may be indirect. This makes it difficult to answer the main research question and therefore this thesis has adopted a three-pronged approach. By achieving consistency in the results of the three separate parts, we hoped to contribute to the reliability of the answer to the research question.

First, we have explored the possibilities of adapting the Dutch Organ Donation Act, with a view to increasing the organ supply. Second, we have assessed the impact of the implementation of the Act and its additional policy measures on the supply of donor organs. And third, we have explored whether a (hypothetical) change to the consent system might lead to an increased donor organ supply.

The results of these analyses are described in section 8.2.1, section 8.2.2, and section 8.2.3 respectively. Based on these findings we will discuss the impact of organ donation legislation and additional policy measures on the supply of donor organs (section 8.3), followed by the conclusion of this thesis (section 8.4). Furthermore, the strengths and limitations of our analyses are discussed (section 8.5). And finally, we will dwell in greater depth on pointers for future research (section 8.6) and the relevance and implications for the policy on organ donation (section 8.7).

8.2 Results of preceding analyses

This section will summarise the main results of the preceding analyses and will answer the three research questions.

8.2.1 To what extent is it possible to adapt the Dutch Organ Donation Act with a view to increasing the supply of donor organs? (Q1)

The Dutch Organ Donation Act has four objectives: (1) to provide legal certainty and to codify the law, (2) to increase the supply of donor organs and tissues, (3) to ensure the fair allocation of donor organs and tissues, and (4) to prevent commercialisation and organ trade.
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The basic idea behind these objectives was that providing legal certainty and trust would change people’s behaviour, leading to increased consent rates, and thus resulting in an increase in the national supply of donor organs. The Act’s main provision to provide legal certainty and trust and to increase the supply of donor organs consists in its consent system based on explicit consent. Other important provisions contributing to the Act’s objectives are the allocation system, provisions for organ donation procedures in hospitals and prohibitions regarding the commercial use of organs. Because the shortage of donor organs persisted even after the introduction of the Act, several proposals to amend the Act were made with a view to increasing the supply of donor-organs and were discussed in a public debate. These proposals concerned adjusting the consent system, introducing non-medical criteria to the allocation system, and introducing financial incentives. Chapter 2 focuses on compliance of the proposals with the principles of physical integrity, non-commerciality and equitable access to care, as laid down in the Declaration on the Promotion of patients’ rights in Europe, the Convention on Human Rights and Biomedicine and its Additional Protocol on Transplantation of Organs and Tissues of Human Origin, and the potential of the proposals to increase the supply of donor organs and reduce waiting time for patients.

General conclusion of part 1
In this part of the thesis we found that the scope for changing the Dutch Organ Donation Act, with a view to increasing the supply of donor organs, is limited. Introducing non-medical criteria, such as reciprocity\(^1\) or the living donor list exchange\(^2\) into the allocation system may infringe on the right of equal access to health care facilities. Introducing financial incentives for organ donation may be at variance with the principle of non-commerciality in organ donation. These potential infringements may harm the trust that people have in the procurement system. Moreover, there is no evidence that the proposed changes will increase the donor organ supply; they may even have a counterproductive effect on the supply of donor organs.

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1. E.g. those who register as donors should be given priority if they are ever on a transplant waiting list.
2. E.g. priority on the waiting list for a post mortem donor organ by offering an organ from a living donor to another person waiting for an organ.
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The principles of physical integrity and equitable access to care do not stand in the way of changing the consent system. Such a change might be considered when it is thought likely that it will increase the number of donor organs. It remains however to be seen whether changing the consent system will have that effect.

8.2.2 What is the impact of the implementation of the Dutch Organ Donation Act and its additional policy measures? (Q2)
To assess the impact of consent systems and additional policy measures on organ procurement, the second part of the thesis focused on the empirical evidence. We assessed the impact of 1) the organ donor policies in ten Western European countries, 2) the policy measures on donor education in the Netherlands, and 3) the implementation of policy measures in Dutch hospitals.

The impact of organ donor policies in ten Western-European countries
A comparison of the impact of policies in ten Western-European countries shows an overall increase in donor efficiency from 1995 to 2005 (chapter 3). Over time, these countries became more efficient in procuring donors, when adjusted for mortality rates relevant for organ donation (e.g. CVA and (traffic) accidents). This means that the efforts to improve donor policies have paid off. The impact of these efforts is partially abated by the success of other policy measures, for instance those directed at reducing the number of traffic accidents. Nonetheless, substantial differences remain between countries in the efficiency of post mortem donor procurement.

The results of chapter 3 indicate that increased donor efficiency is not related to having a presumed consent system. We did not find consistent differences between consent systems, nor did we find that the donor procurement rates of presumed consent countries (adjusted for relevant mortality) increased more rapidly than those of explicit consent countries (Figure 8.1).

Particularly relevant to our analysis are the reports of countries that introduced a new consent system or changed their system (Figure 8.2). These countries show no consistent effect on their efficiency in donor procurement. Germany enacted an explicit consent system in 1997 and the Netherlands enacted its explicit consent system in 1998. In Germany we see that the
efficiency of donor procurement was already increasing; there are no differences between the trends before and after the enactment of the consent system. In the Netherlands, however, we see that the efficiency of donor procurement was already declining, and one year after the enactment, the efficiency in donor procurement reached an all-time low. From 2001 on, the efficiency in donor procurement increased.

There are also countries which switched to a presumed consent system between 1995 and 2005. Sweden changed from an explicit consent system to a presumed consent system in 1996. This change led to a temporary increase in the efficiency of donor procurement. Italy changed from explicit consent to presumed consent in 1999. For Italy we see, as in the case of Germany, that the efficiency of donor procurement was already increasing and that there are no differences between the trends before and after changing the consent system.

For most countries, the national policies on organ donation are “black boxes”; it is difficult to gain insight into the strategies of governments and the additional policy measures implemented over a period of several years. It remains unclear which specific policy measures are responsible for increased donor efficiency rates.

To gain insight into this black box and to explain the trend of donor procurement in the Netherlands, we tried to disentangle the Dutch strategy and the additional policy measures from the impact on the supply of donor organs. To increase the consent rates for organ donation, the government developed a strategy with additional policy measures that focused on providing donor education to the public (chapter 4) and on increasing the efficiency of the process of organ donation in hospitals (chapter 5).
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Figure 8.1  The efficiency of post mortem donor procurement in 10 European countries*

![Graph showing donor efficiency rates by proxy for 10 European countries from 1995 to 2005.](image)

Source: R. Coppen et al., 2008

* Donation rates adjusted for mortality rates which are relevant for organ donation 1995-2005
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Figure 8.2  The efficiency of donor procurement in 4 European countries that introduced a new consent system or changed their system*

Source: R.Coppen et al., 2008
*  Donation rates adjusted for mortality rates which are relevant for organ donation 1995-2005

The impact of the policy measures on donor education
The introduction of the Dutch Organ Donation Act (1998) was accompanied by several rather fragmented donor education campaigns which merely informed people about organ donation and registration (chapter 4). One year after the enactment of the Act, the national donation rates dropped from 216 post mortem donors in 1997 (13.8 donors per million inhabitants (PMI) to an all-time low of 165 donors in 1999 (10.4 donors PMI) (Nederlandse Transplantatie Stichting, 2000; Nederlandse Transplantatie Stichting, 2007). Because of these disappointing donor rates the government initiated a plan of action for organ donation in 2000. This initiative proposed cohesive sustained and comprehensive multi-channel campaigns with a
focus on persuading people to register consent. In 2004, an extensive public debate about the donor organ shortage and the Dutch consent system took place. In anticipation of this public debate, a sustained and comprehensive multi-channel campaign was conducted, which included mass media interventions and several mail shots of donor registration forms. By assessing the effects of the policy measures in the field of donor education, chapter 4 shows that this change in strategy led to an increase in registrations. It seems that putting effort into donor education had paid off. The positive correlation between (consent) registrations and donor procurement underlines the importance of maximising the number of consent registrations in an explicit consent system. We also found some noteworthy fluctuation in the efficiency of donor procurement in 2007. This fluctuation cannot be explained by the implementation of policy measures or changes in the organisational or legal system. When interpreting donor procurement rates it is important to bear in mind that they can fluctuate between years. Despite intensified efforts to carry out donor education campaigns, the effects of campaigns seem to level off over time. Because it is unknown how much room there is for an improvement in donation and registration rates, it is unclear what effects may be expected from future policy measures.

The impact of the implementation of policy measures in hospitals
Donation rates vary among Dutch hospitals. When comparing 80 hospitals (chapter 5), most of the variation in numbers of organ donors can be explained by the hospital-specific mortality statistics. It was found that 81% of all donors came from one quarter of the hospitals, mainly larger hospitals. This strong correlation between mortality and number of donors implies that hospitals with many potential donors also utilise this potential; there are no large undiscovered and unused pools of donor organs.

There are many smaller hospitals with relatively low mortality rates for organ donation, that have small numbers of donors, whereas the (larger) hospitals with high mortality rates for organ donation have more donors. We also found that some larger hospitals performed less well on organ procurement than others. Seven hospitals systematically underperformed over a period of 5 years.
These findings suggest that, despite the absence of large undiscovered and unused pools of donor organs, there still seems to be room for improvement in certain hospitals. We found that the degree of policy implementation or the presence of a donation officer within a hospital do not significantly increase donation rates in hospitals. Hospitals with a neurosurgery department had extra donors. A more in-depth analysis may provide clues as to how donor procurement in underperforming hospitals can be improved.

**General conclusion of part 2**

One year after the introduction of the Act, the efficiency of donor procurement dropped (Figure 8.2). Apparently, the impact of legislation on the supply of organ donation was insufficient and subsequently additional policy measures were implemented. In general, these additional policy measures led to a steady increase in the efficiency of donor procurement (chapters 3 and 4). According to the findings of chapters 3, 4, and 5 it is expected that improvements in the efficiency of donor procurement will only be modest. Notwithstanding that, each additional donor is an important contribution to shortening the waiting list for donor organs.

### 8.2.3 Will changing or adjusting the current consent system influence the donor organ supply? (Q3)

*The impact of consent systems in ten Western European countries*

The first part of our analysis concludes that theoretically there is room to change the consent system. This last part of our analysis focuses on what effects can be expected from changing the consent system. The higher donation rates of countries with presumed consent systems seem to prove the assumption that countries with large pools of presumed donors are more effective than countries with much smaller pools of explicit donors. However, we found that differences in donation rates between countries can be explained by differences in mortality rates, e.g. causes of death that are relevant for organ donation such as CVA or (traffic) accidents. When adjusting the donation rates for these differences in mortality rates the difference between presumed consent and explicit consent countries disappears (chapter 6).
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*Imagining the impact of consent systems on organ donation*

The pool of possible donors in presumed consent systems is much larger than the donor pool in explicit consent systems. However, there are no clear differences in the efficiency of donor procurement between presumed and explicit consent countries (chapters 3 and 6). How can the absence of differences be explained? Formally, next of kin are only consulted in an explicit consent system when the potential donor is not registered. Next of kin need not be consulted when a potential donor is not registered in a presumed consent system. Nonetheless, several studies have found that in practice next of kin are always consulted (Childress & Liverman, 2006; Chouhan & Draper, 2003; Galea & Pegg, 2003; Gevers, Janssen, & Friele, 2004; Janssen & Gevers, 2005; Matesanz, 1998; Prottas, 1985). The predominant role of next of kin, where no decision by the deceased has been recorded (as is most frequent in both presumed as well as explicit consent countries), reduces the potential of the presumed consent system. Because next of kin play such an important role in both systems, a large donor pool filled with presumed consents will result in a much smaller pool of donors if next of kin withhold their approval. On the other hand, countries with a small donor pool filled with explicit consents may suffer far less from this phenomenon if next of kin follow the explicit wishes of the deceased.

We found that people say they are more likely to agree to donate organs of explicit than of presumed donors (chapter 7). The degree to which deceased made their consent explicit, influences next of kin in their decisions. Thus, in a presumed consent system, the pool of (presumed) consenting donors is large, but the likelihood that next of kin will agree with donation is lower; in an explicit consent system the pool of (explicit) consenting donors is small, but the likelihood that next of kin will agree is larger. This variation might explain the absence of differences in efficiency between consent systems. Furthermore, a noteworthy observation in this study is that about two-thirds of the Dutch respondents report that they would not approve a consent system in which they (as next of kin) are not consulted. The respondents, in their imagined role as next of kin, indicate that the more they are convinced that organ donation is exactly what the potential donor wanted, the less importance they attach to being involved in the decision-making process. It seems that the respondents experience more confidence in donating organs
when consent is made more explicit.

General conclusion of part 3
Differences in organ donation rates between consent systems disappear when these rates are adjusted for an important confounder; i.e. differences in relevant mortality rates between countries. The absence of influence by the formal consent system can be explained by the role of next of kin in donation procedures. Other studies demonstrated that in general next of kin are consulted. This study adds to this finding that next of kin seem to differentiate between presumed and explicit donors. As people say they are more likely to agree to donate organs of explicit than of presumed donors, it is unlikely that changing the system will increase the supply of donor organs. This leads to the conclusion that the impact of consent systems on the supply of donor organs is only limited and that introducing a presumed consent system in the Netherlands will not guarantee higher donation rates.

8.3 Discussion
What do the conclusions of the three different parts of this thesis mean for the main research question? What is the impact of organ donation legislation and additional policy measures on the supply of donor organs? And how can we explain our results?

8.3.1 The impact of explicit consent systems on the supply of donor organs
Opting for the current explicit consent system is for a large part based on the basic idea that safeguarding the right to physical integrity by law is important and essential for people’s trust in organ procurement. In the Netherlands, creating trust in organ procurement was considered to be a necessary condition for increasing the supply of donor organs. According to this view, the impact of the consent system on the supply of donor organs depends on the impact on the people’s trust in organ procurement. However, the correlation between the introduction of the Act’s consent system and its impact on the supply of donor organs is rather indirect and there is no empirical evidence that there is a relationship between creating
trust in organ procurement through legislation on organ donation and increasing the supply of donor organs.

8.3.2 The impact of presumed consent systems on the supply of donor organs
Countries with presumed consent systems have higher donation rates than countries with explicit consent systems. It is tempting to ascribe these higher donation rates to the larger pool of possible donors in presumed consent systems (based on raw statistics). As the introduction of the Dutch organ Donation Act in 1998 did not increase the donation rates in the Netherlands, it was proposed to enact a presumed consent system or a system with automatic donor registration.

Although countries with presumed consent systems have higher donation rates than countries with explicit consent systems, we cannot confirm that these higher rates are the result of having a presumed consent system. This thesis demonstrates that the differences in donation rates between presumed consent countries and explicit consent countries are explained by their differences in mortality rates that are relevant for organ donation. When adjusting the donation rates for these differences the potential of presumed consent countries for higher donation rates disappears. We found that in explicit as well as presumed consent systems next of kin play a role in obtaining consent for organ donation. Involving next of kin in the procurement procedure is standard practice in each Western European country. Apparently, the medical staff do not comply with the rule that the absence of a refusal implies consent. As a result, presumed consent and explicit consent systems are more similar than assumed by their distinction (Gevers et al., 2004) and, therefore produce similar results.

8.3.3 The impact of legislation in general
Although the Dutch Organ Donation Act did not lead to an increased donor organ supply, enacting legislation on organ donation was considered important to create legal certainty and trust in organ donation procedures (the first objective of the Act). To support the further objective of the Act - increasing the supply of donor organs - additional policy measures were needed. It seems that in this case, legislation alone was not sufficiently effective in increasing the number of donor organs. This observation raises a
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broader question regarding the potential of legislation as an instrument for change. The complex relationship between legislation and change has also been highlighted by others.

One of the elements in the complex relationship between legislation and change is time. The first evaluation in 2001 of the Dutch Act on Medical Examinations, three years after its enactment, reported a limited impact. In 2007 the second evaluation reports that the Act is indeed rather effective (Klein Haarhuis & Niemeijer, 2008). Sometimes it takes a considerable length of time for legislation to have impact. One of the reasons may be that it may take time for its target population to become familiar with the Act, and to change their behaviour accordingly (Klein Haarhuis et al., 2008). But time is not the sole factor influencing the relationship between legislation and change.

In another example in health care regulation on the position of the patient, it appears that the relationship between a legal provision and its intended impact is somewhat indirect. Friele discusses the position of the patient by focussing on the impact of informed consent (laid down by the Medical Treatment Agreement Act), the freedom of choice (laid down by the Health Insurance Act), and medical complaints (laid down by the Health Care Complaints Act). He concludes that although these Acts are supported by both medical professionals as well as patients, in reality their impact on the position of the patient is (still?) limited (Friele, 2009). It seems that the limited impact of legal instruments on the position of the patient can be explained by the complexity of the legal provisions. Furthermore, in the case of the Medical Treatment Agreement Act it is not easy to enforce compliance with its provisions in practice and the provisions do not always meet the real demands of patients (Friele, 2009).

This limited impact of legislation is not only seen within the health care sector. According to an overview of 58 Dutch law evaluations only 11 evaluations concluded that the objectives of the evaluated Act were predominantly met. Six evaluations even concluded that the objectives of the evaluated Act were hardly met. The remaining 41 evaluations concluded that only some of the objectives were met (Klein Haarhuis et al., 2008). The enactment of legislation only will usually not be enough to have an impact, and time and law enforcement are necessary.
8.3.4 The impact of additional policy measures
Although legal systems alone seem to have only limited impact on the supply of donor organs, we did find that additional policy measures do have an impact. One year after the enactment of the Act the efficiency of donor procurement reached its all-time low (Figure 8.3) and the Dutch government developed a strategy to increase the efficiency of donor procurement by implementing additional policy measures. From 2000 on we see that the efficiency of donor procurement in the Netherlands increased slightly. This increase seems to demonstrate that implementing these measures has paid off (see Figure 8.3).

Figure 8.3 Donor procurement in the Netherlands shown by the donor rates adjusted for differences in relevant mortality rates between years (1997-2008)

1. Introduction of the Act in 1998
2. Plan of Action on organ donation in 2000
3. Capitalisation of donor education on the massive public debate
4. Trendline

8.4 Conclusion
Although it is difficult to assess the impact of legislation alone on the supply of donor organs, it seems that this impact is only limited. The enactment of the Dutch consent system, based on explicit consent, did not lead to an increase in the supply of post mortem donor organs. Additional policy measures were needed to realise this increase. However, it is important to acknowledge that the Act forms an important legal basis for the
implementation of the additional policy measures and determines their scope. The Organ Donation Act provides legal certainty to potential donors, their next of kin, patients waiting for an organ, and medical staff. Public trust in organ donation procedures is still considered to be an important condition for policy measures designed to increase procurement rates.

To support the impact of legislation on organ donation and to optimally use the room for improvement of organ procurement, the implementation of additional policy measures is essential. We found that additional policy measures have an impact on the supply of donor organs, or at least support the instrumental function of legislation on organ donation. Since the introduction of the Dutch Organ Donation Act and the implementation of additional policy measures the donor rates (adjusted for differences in relevant mortality rates between years) have increased gradually. Finally, we found no indications that introducing a presumed consent system in the Netherlands would lead to higher donation rates. Changing to another consent system will possibly not increase the organ supply in the Netherlands.

8.5 Strengths and limitations of this study

Assessing the impact of the legal system and additional policy measures on the supply of donor organs was challenging, and some difficulties had to be dealt with. A first (methodological) difficulty is that national strategies, such as the implementation of the Dutch Organ Donation Act, cannot be the subject of an experimental design. It is unthinkable to divide a country’s population into an experimental group and a control group. This would cause (legal) inequality; the chance of receiving an organ would be larger for one of the groups. Furthermore, when evaluating the impact of legislation pre- and post-measurements are often missing because the enactment of legislation is often an offshoot of existing governmental policies. A second difficulty is that the effects of legislation are blurred by external factors. These factors may cause differences in organ donation rates between years, regions or hospitals within a country, or between countries. Examples of such factors are the number of potential donors of a hospital or a country, hospital based factors (e.g. size, operating room capacity), or cultural
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differences between countries. Hence, the impact of an Act and additional policy measures is rather diffuse (Klein Haarhuis et al., 2008). A third difficulty is that an Act and its additional policy measures are often intertwined. Several provisions of the Act and the additional policy measures aim to reach the same effect.

An Act is part of a legal system. The impact of an Act cannot be seen apart from the impact of other pieces of legislation and its place in the legal system as a whole. Besides, the legal system and additional policy measures evolve over time. Moreover, legislation also needs time to have an effect on society. It takes time before its target population is familiar with the Act and is willing and able to use the Act.Attributing effects to an Act or part of it is difficult and should be done with great caution.

To overcome these difficulties we addressed the problem from three different angles, (1) an exploration of the possibilities to adapt the Act, (2) an assessment of the impact of the implementation of the Act and its additional policy measures, (3) an exploration of whether a virtual change of the consent system might lead to an increase in the donor organ supply. In doing so we used different techniques including international comparative research, and assessments of the impact of donor legislation and additional policy measures over time. When comparing donation rates between hospitals, countries, and even years, it is important to adjust for differences in relevant mortality rates. The donor rates in our studies (chapters 3, 4, 5, 6) were therefore adjusted for the confounding effects of relevant mortality. Because legislation needs time to have an effect on society it was also important to include time series in some of our studies (chapters 3 and 4).

The strengths and limitations of the separate studies of this thesis have been described in the consecutive chapters. The results of the three different parts are consistent and, therefore, we believe they give a reliable answer to our research question.

This thesis focuses on the problematic shortage of donor organs and questions regarding the limited ability of the legislation to solve this shortage. A limitation of this thesis is, therefore, that it focuses strongly on only one of the Act’s objectives, i.e. to increase the supply of donor organs, and more specifically on one of its provisions - its explicit consent system. Accordingly, this thesis does not provide a full discussion of the functioning
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of the Act. We did not assess the aspects of the Act regarding the fair allocation of donor organs, nor issues related to the trade in donor organs. Furthermore, we limited ourselves to post mortem donation, whereas living donation is developing at a very fast rate. Finally, we did not pay attention to the symbolic function of legislation, i.e. the potential of legislation on organ donation to express such values as solidarity with patients in need of organ transplantation (see Box 8.1), or to instigate changes in policy making or social behaviour.

Box 8.1 The symbolic function of the Dutch Organ Donation Act: expressing solidarity to patients in need of an organ

People waiting for an organ depend on the solidarity of others to start a new life. The current consent system delegates the responsibility for showing solidarity with patients waiting for an organ to each individual. Individuals are responsible for their own consent registration.

Where does the Dutch population stand on solidarity with people waiting for an organ? On the one hand, 5.4 million people (approximately 40% of the adults in the Netherlands) are registered in the Donor Register and approximately 3 million people have explicitly registered their consent. With such high registration rates the Netherlands has the world’s largest donor registration. On the other hand, approximately 60% did not register, which may suggest that these persons are not committed to organ donation or find it difficult to make a decision on whether or not to be a donor and to formalise this decision. Still, as anyone could need an organ, the commitment, as suggested by the number of registered consents, seems to be rather low. The results of several survey studies, however, indicate that 90% of the Dutch population supports organ donation (Cox, 2005; Ipso Facto, 2000; Verzijden & Schothorst, 2003; Zijdenbosch & Lutterveld, 1997; Zijdenbosch & Kamphuis, 1998).

Hence, these findings give a contradictory answer to the question of where the Dutch population stands on solidarity with organ donation. According to Nys, explicit consent systems are the expression of societies comprising isolated, independent individuals who make informed choices on their own, whereas presumed consent systems express the commitment and solidarity of people with organ donation (Nys, 2004). In presumed consent systems the solidarity of people with organ donation is arranged at community level.

- Box 8.1 To be continued -
Also the alternative system for consent registration (the automatic consent registration), in which people are automatically registered after several personal reminders, regulates solidarity of people at community level. In this alternative system the current explicit consent registrations are maintained. A change to a system with presumed consent aspects, such as the alternative system for consent registration, could be seen as an expression of the commitment and solidarity of healthy people to those waiting for an organ.

As a relatively small group of people in desperate need of a donor organ depends on a large group of people who may seem to be reluctant to register their consent and to express their solidarity, this raises questions on how to organise solidarity in organ donation. Some people will say that because of the weak position of the people waiting for an organ, organ donation should be organised on community level rather than on the individual level. It remains unknown whether changing to another consent system will have a positive effect on public trust in the organ procurement system or will harm that trust and may even backfire on the supply of donor organs. Changing to another consent system demands in-depth study on its possible effects on this topic, including the symbolic function of legislation.

8.6 Directions for future research

The importance of adjusting donation rates for differences in relevant mortality rates

Although donor procurement is a complex process influenced by several external factors, the impact of consent systems on donor procurement is often assessed by comparing donation rates between countries or years. Failure to adjust donation rates for important confounding factors may result in false conclusions. We found a strong correlation between donation rates and relevant mortality for organ donation (CVA and (traffic) accidents) when comparing 10 Western European countries. Hence, this thesis addresses the importance of adjusting donation rates for differences in relevant mortality rates when comparing the impact of donor policies between countries or years. It remains unknown whether other differences between countries explain discrepancies in organ donation rates and whether our results are also applicable for countries other than these ten.
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Family refusal as an outcome measure when assessing donor education policy
An important factor in the loss of potential donors is family refusal. Several policy measures aim at reducing family refusal. For this reason, the impact of these policy measures should be assessed by their effect not only on registration rates and donor procurement rates, but also on refusal rates. Since 2006 the Dutch Transplant Foundation (NTS) publishes national refusal rates. This enables future research to assess trends in refusal rates and may shed more light on the impact of policy measures.

Suggestions for the assessment of the impact of legislation
Expectations regarding the impact of legislation are high. Improved insight into how legislation impacts on society may contribute to more realistic expectations of legislation and may lead to better quality of legislation (Veerman, 2004; Winter, 1997). In this thesis on the impact of organ donor legislation we encountered some issues that may be relevant not only for the assessment of legislation on organ donation, but also for studying the impact of health legislation in general.

Firstly, when evaluating the impact of legislation it is important to also take account of the impact of additional policy measures. We found that the introduction of the Dutch Organ Donation Act alone did not increase the organ supply. Apparently, the Organ Donation Act on its own could not realise a change in this part of health care. Additional policy measures were needed to create an impact. Other evaluations of health law likewise report the importance of taking additional policy measures into account. Winter, for example, concludes that compliance with the Dutch Psychiatric Hospitals Compulsory Admissions Act three years after its introduction was still limited; its provisions were not clear to professionals (Winter, 1997). Professionals had to be educated about the provisions of the Psychiatric Hospitals Compulsory Admissions Act. The impact of the intensified education on compliance with the Act was assessed by its second and third evaluation (Derde evaluatiecommissie van de Wet Bopz, 2007). Furthermore, the relationship between an Act, its additional policy measures, and their impact is rather complex. The effects of legislation are often rather indirect and are often intertwined with the effects of other policy measures. On top of this, national policies tend to be vague and policy objectives may change over time. This makes it even more difficult for a researcher to assess the
impact of legislation and policy measures (Kroneman & van der Zee, 1997). When studying the impact of legislation it is important to develop a strategy that addresses this interdependence of laws and policy measures. In this study we assessed the impact of additional policy measures over time. Because the introduction of the Act was followed by a phased introduction of additional policy measures we were able to assess the individual phases. Secondly, the evaluation of laws often demands a multidisciplinary research approach. After all, legislation has an impact on different aspects of society. This multidisciplinary research approach should result in combining the findings of various disciplines and formulating an unambiguous conclusion. The approach taken in this thesis is from the perspective of the underlying problem: the donor organ shortage and the impact of legislation and policy measures on this shortage. Our study has focused on the legal aspects (chapter 2), effects on macro-level (on the national and international level - chapters 3, 4, and 6), effects on meso-level (organisations - chapter 5), and effects on micro-level (individuals - chapter 7). As it turned out, this thesis has resulted in an unambiguous conclusion, due to the different approaches of the separate studies.

Thirdly, when assessing empirical effects an outcome indicator, a baseline-measurement and a control group are essential. In our evaluation of the impact of the Dutch Organ Donation Act we were able to use an outcome indicator: donation rates which were adjusted for differences in mortality rates between years. Besides, measuring organ donation rates was already common practice before the enactment of the Dutch Organ Donation Act and pre- and baseline-measurements were available. For that reason it was possible to assess the impact of the introduction of the Act and of its effects over time. This enabled us to ascertain a decline in donation rates in the initial period following enactment. To enable valid evaluations of health law, such data are vital. They may be found in data already collected routinely, as was the case in this study. But there is no guarantee that such data will always be available. To be able to assess the real impact of legislation, data should therefore be gathered in advance, e.g. by pre- and baseline-measurements. Furthermore, assessing the impact of an Act over time raises questions about the lapse of time between the introduction of the legislation and its first evaluation. It also raises questions about the frequency of law evaluations. As discussed earlier, it may take a
considerable length of time for legislation to have an effect. When interpreting the findings of evaluations of health law it should be established how much impact is realistic to expect, taking the time factor into account. In addition, controls are always difficult to create when evaluating health law. It is unthinkable that an experimental and a control group could be created within one country. As a second best approach we used other countries, and the impact of their donor policies, as a proxy. This strategy proved to be useful to assess the impact of consent systems on donor procurement. It also demonstrated the importance of taking into account confounding factors leading to differences between countries (e.g. differences in relevant mortality rates (such as CVA and (traffic) accidents)).

These issues show that there is a large variety in methodological issues. And there will be more issues when assessing the impact of laws (Winter, 1997); each law evaluation requires its own tailored method. At the same time, a common perspective on how to perform law evaluations is needed to be able to compare findings on the impact of legislation. This requires further development of the methodology.

8.7 Relevance and implications for the policy on organ donation

Some 1,300 patients are waiting for an organ in the Netherlands, for the larger part kidney patients (approximately 950) (Nederlandse Transplantatie Stichting, 2009), whereas there are only around 200 post mortem organ donors a year. For the people waiting for an organ the availability of donor organs is of major importance. Receiving a donor organ makes a difference between living as a patient and being dependent on dialysis or living as a relatively healthy person.

In this thesis (chapter 2) we have found that there is room, taking into account national and international fundamental legal principles, to change to another consent system. Many consider changing from the current explicit consent system to a presumed consent system, or adjusting the current system to automatic consent registration, to be the best option for increasing the donor organ supply. However, we have also found (chapters 3, 6) that
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there is no empirical evidence that such a change will lead to a substantial increase in organ supply. We conclude that it is not likely that the gap between the number of people who need an organ and the number of post mortem donor organs will be reduced by changing to another consent system. The instrumental effects of legislation alone are limited. Nor did we encounter other policy measures that could easily solve the donor organ shortage. Chapter 7 even indicates that changing to a presumed consent system may cause an increase of family refusals. That changing the policy on post mortem organ donation is not a magic bullet to solve the organ shortage is a disappointing message for those waiting for an organ.

Recommendations for policies on organ donation

Although the instrumental impact of legislation on the supply of donor organs is limited, we did find that the implementation of additional policy measures has an effect on increasing the organ supply. Putting efforts into additional policy measures is therefore important. Still, even the impact of additional policy measures is at best limited in solving the organ shortage. Furthermore, it is important to keep in mind that some policy measures may only have a one-off effect and that the effects of policy measures level off over time. We observed a one-off fluctuation in Dutch (adjusted) donation rates in 2007 which cannot be explained by the implementation of policy measures or changes in the organisational or legal system. This indicates that as yet unknown mechanisms have an impact on donor procurement. Regular evaluation of the impact of policy measures on the supply of organs is important to monitor developments and may yield pointers for making adjustments in order to optimise the impact and eventually increase the organ supply.

The findings of this thesis indicate that next of kin play an important role in donor procurement. As about two-thirds of our respondents would not approve a consent system in which they (as next of kin) are not consulted, it seems important to take the role of next of kin into account when drafting policy measures. In the Netherlands, when a deceased person registered consent in the National Donor Register 10% of next of kin still refused consent for the removal of organs. When no registration of consent or refusal is available as many as 68% of next of kin refuse permission for the removal
General discussion and conclusions

of organs (Friele et al., 2004). Furthermore, we found a strong correlation between the number of consent registrations and donor procurement rates. However, there is no systematic insight into the effectiveness of measures regarding donor education and communication (Friele, Gevers, Blok, Coppen, & Smit, 2006). It is unknown what donor rates and efficiency in donor procurement rates are realistic targets.

Finally, we also found that there are differences in the efficiency of donor procurement between larger hospitals. These differences cannot be explained by structural factors (such as the degree of policy implementation or the presence of a donation officer). This suggests that for some hospitals there is still room for improvement. To determine which factors may increase donor procurement in the hospitals it is necessary to conduct a more in-depth analysis of the differences in donor procurement and policy measures in the larger hospitals. This will also give hospitals the opportunity to exchange best practices on donor procurement.

This leads to three recommendations for policy making on organ donation. Firstly, the number of consent registrations should be maximised. More consent registrations will lead to fewer family refusals. Secondly, the role of the family should always be taken into account when new policy measures are being drafted. Moreover, it is important to keep developing policy measures which focus on the role of next of kin and monitor their impact on family-refusal rates. And thirdly, it is important to monitor which larger hospitals still have room for improving their efficiency in the donor procurement process and to assess how this process can be improved.

8.8 Final remarks

We are aware that our findings convey a disappointing message to people waiting for an organ. After all, the shortage remains and the gap between the supply of post mortem donor organs and people waiting for an organ is large. The theoretical maximum post mortem donor potential in the Netherlands is 500-550 (Ploeg et al., 2003; Friele & Kerssens, 2004; Friele & Jong, 2007). Despite various strategies to maximise the number of post mortem donor organs, there are only some 200 organ donors on a yearly basis, while approximately 1,300 people are waiting for an organ. In both
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Dutch as well as international studies we did not discover strategies, which are not yet implemented in the Netherlands, that show large increases in post mortem organ donation. Therefore, it seems unlikely that this gap can be closed by organ donation post mortem. Improvements to the post mortem organ supply will be modest.

In the meantime, the government cannot ignore this problem. Waiting lists may increase and people on these waiting lists may not survive lengthy waiting periods. It is likely that some of those in need of an organ will search for alternative ways to find a donor. Adverse consequences, such as organ-tourism, may thus arise. It is important for countries to put effort in increasing their supply of donor organs (Caplan, Domínguez-Gil, Matesanz, & Prior, 2009).

An effective (but unthinkable) strategy to increase the number of potential donors and consequently the supply of donor organs would be to become less strict on traffic safety. This is of course not realistic. Another strategy would be to adopt a consent system in which next of kin cannot obstruct the donation of organs, but our findings indicate that such a strategy would also meet with serious objections in the Netherlands.

Are there no options at all to increase the supply of donor organs? A large part of the Dutch population has a positive attitude to organ donation, but family refusal rates for organ donation are high. This suggests that improvement and refinement of donor communication and education may increase the supply. Notwithstanding that, the consent procedure takes place under emotional and stressful conditions. We also see some other developments. First of all, the number of living donations has increased over the years. In 2008, the number of kidney transplants from a living donor (411 kidneys) for the first time exceeded the number of kidney transplants from a post mortem donor (352 kidneys) in the Netherlands (Nederlandse Transplantatie Stichting, 2009). Apparently, living donation is considered to be an alternative source for some organs. Secondly, in the long run, the development of artificial organs may provide an alternative source for donor organs. For the immediate future, however, there is no magic bullet to solve the organ shortage problem.