

## ORIGINAL ARTICLE

# How large is the organ donor potential in Germany? Results of an analysis of data collected on deceased with primary and secondary brain damage in intensive care unit from 2002 to 2005

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data analysis, deceased, organ donation, organ donation potential, potential/effective donors, refusal rate.

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## Summary

The number of potential organ donors depends on various factors, among which the number of deceased with primary or secondary brain damage is the most decisive. In the north-east donor region of Germany with 7.69 million inhabitants, 2019 cases of deceased with primary or secondary brain damage were reported by 136 intensive care units during 2002–2005. In a study, 64% of these deceased were identified as potential donors. This represents 40.7 potential donors per million inhabitants. It can be concluded that in the other donor regions of Germany a comparable number of potential donors exists, yet not all possible donors are being detected and referred. The conversion rate (percentage of potential donors who become effective donors) in the years 2002–2005 was 47%. The main reason for the conversion rate being so low was the large number of relatives who declined an organ donation (73%). More than 90% of the relatives in the north-east region did not know the deceased's will in the acute situation. From our point of view the high refusal rate can be decreased mainly by two measures: improvement of the family approach and integrating the topic of organ donation into schools' curricula.

## Introduction

At the present time, approximately 12 000 patients are waiting for an organ transplant in Germany and more than 1000 persons die each year because they do not receive a transplant in time. The main reason for this unsatisfactory situation is the lack of donor organs.

When the Transplantation Law came into effect in 1997, it was expected that the number of organ donations would increase substantially and the waiting time for transplantation would be shortened. But the desired increase failed to materialize. The law regulates the donation, removal, allocation, and transplantation of organs

from deceased and living donors in Germany. The law provides for an extended consent solution (opt-in-policy): The deceased's decision for or against an organ donation during his or her lifetime takes precedence. If this decision has not been documented (e.g. on an organ donor card) or is not known, the next of kin decide about an organ donation based on the presumed will of the deceased.

The 1400 German hospitals with intensive care units (ICUs) are obliged to refer possible donors. Presently, about 45% of these hospitals meet this legal requirement. The law also stipulates that an independent organization co-ordinate organ donations in co-operation with the

	2002	2003	2004	2005
Baden-Wuerttemberg	9.8	13.2	12.0	12.9
Bavaria	14.8	14.9	13.2	18.1
Central (Hesse, Rhineland-Palatine, Saarland)	9.3	12.7	13.7	13.2
North (Bremen, Hamburg, Lower Saxony, Schleswig-Holstein)	12.6	13.0	13.9	13.8
North-East (Berlin, Brandenburg, Mecklenburg-Western Pomerania)	19.5	18.4	20.2	23.1
North Rhine-Westfalia	11.3	11.1	8.6	10.9
East (Saxony, Saxony-Anhalt, Thuringia)	12.4	17.3	15.4	16.7
<b>Germany</b>	<b>12.5</b>	<b>13.8</b>	<b>13.1</b>	<b>14.8</b>

**Table 1.** Development of organ donation p.m.p. in the seven organ donor regions from the years 2002 to 2005 (the calculation was performed according to the donor definition of the DSO valid at that time).

hospitals and transplantation centres. In 2000 the German Organ Transplantation Foundation [Deutsche Stiftung Organtransplantation (DSO); established in 1984] became the federal/national co-ordinating organ procurement organization. In order to support hospitals as promptly as possible, DSO established seven donor regions offering consultation and assistance with donor evaluation, diagnosis of brain death, donor management, donor examinations, and family approach. Furthermore, DSO organises organ removal and transmits the donor data to Eurotransplant, the Dutch foundation for the allocation of organs. The German Medical Association has established the criteria for organ allocation and the regulations for diagnosing brain death. DSO operates offices in the seven donor regions with 24-h hotlines and a total of about 63 transplant co-ordinators. Despite having comparable structures in place in each of the DSO donor regions, the number of effective organ donations per million persons/inhabitants (p.m.p.) shows considerable differences among the seven regions (Table 1).

Due to the lack of epidemiological studies, statements with regard to the number of potential organ donors and the circumstances that stand in the way of realization in Germany are not possible. Therefore, the reasons for the disparate donor rates in the seven organ donor regions cannot be explained either. Cognisance of the number of potential organ donors and the circumstances that prevent realization allows not only appropriate measures to be taken to increase organ donation, but also points out the limitations of transplantation medicine under 'ideal' conditions.

In a retrospective study in seven hospitals in Hamburg with a total of 16 ICUs, Ohm *et al.* [1] could show that, the number of organ donations implemented in 1998 could have been increased by 100%. This investigation confirms the assumption that the organ donor potential in Germany must be as high as that in the USA (between 38.3 and 55.2 potential organ donors p.m.p.), Spain (57), and France (62) [2–4].

The determination of the number of potential organ donors in the hospitals of the above-mentioned countries was performed retrospectively using the hospital register

and inspection of the medical records from the ICU. This method is very cost- and labour-intensive and presupposes good patient documentation.

The objective of this study was to record the number of potential organ donors in the north-east region promptly and continuously using a simple method, and to analyse the reasons that prevented actual donations.

## Methods

The north-east donor region includes the states of Berlin, Brandenburg and Mecklenburg–Western Pomerania and had a population of 7.67 million persons in 2005 [Federal Statistics Office, 30 June 2005]. There are 119 hospitals in these three states with 136 ICUs, of which three are university hospitals and 13 are hospitals with neurosurgical departments. A form was designed to collect the data (Fig. 1); the physicians responsible in the ICUs were to return the completed form to the central office of the federal organ procurement organisation (DSO) in the north-east region every month, where medical co-ordinators checked it for plausibility and entered the data into the database. The request for continuous data collection was discussed with the hospital management and the ICU doctors in advance, and the procedures were co-ordinated. Data protection authorities of the three states gave their approval for data collection using this form.

Deceased with primary or secondary brain damage in the ICUs were included regardless of age. The form is being filled out at the same time as the death certificate, and this takes about 5 minutes. Data entry forms with the statement – 'no primary or secondary brain damage in the deceased' – were not included in the evaluation.

*Possible organ donors* were defined as those deceased for whom no medical contraindications to organ donation existed (see data entry form, question 11), and *potential donors* were defined as those for whom the diagnosis of brain death had been initiated and/or completed and no contraindications existed. Donors with consent or *consented donors* were considered to be those who were medically suitable for organ donation, for whom brain death had been definitively diagnosed, and where consent for

**Form for data entry about deceased with primary or secondary brain damage in the intensive care unit**

1. Hospital \_\_\_\_\_ 2. Department \_\_\_\_\_

3. No deaths during the month \_\_\_\_\_ 4. Admission No./Medical record No.: \_\_\_\_\_

5. Sex  female  male 6. Age \_\_\_\_\_

7. ICD-10 diagnosis as indicated on the death certificate \_\_\_\_\_

8. Traumatic brain damage  Yes  No

9. Length of time in intensive care unit Hours \_\_\_\_\_ (for <1 day) Days \_\_\_\_\_

10. Date of death Month/Year \_\_\_\_\_

11. Are there any medical contraindications to organ donation?

No **Yes**

Non-curatively treated malignancy  Florid tuberculosis  HIV infection

Confirmation of multi-resistant microbes or fungi in the blood

Systemic infection with multi-organ failure

Other reasons / Remarks \_\_\_\_\_

12. Was brain death determination initiated?

Yes **No**

Circulation could not be stabilised <=6 h after admission to ICU

Sudden and unexpected circulatory failure during therapy

Circulatory failure in the case of poor prognosis of brain damage with additional complications (e.g. pneumonia)

13. Was the determination of brain death completed?

Yes **No**

Circulatory failure in the case of non-complete loss of brainstem reflexes and / or apnoea test negative

Circulatory failure during the observation time

No second examiner

No apparative additional diagnostics

14. Was organ donation discussed with the relatives?

Yes **No**

Personal data of the patient not able to be determined

No identifiable relatives

Relatives not contacted

Questioning of the relatives unacceptable

15. Who conducted the discussion with the relatives?

Director  Department Head  Unit Physician  Nurse  Co-ordinator

(More than one option can be checked)

16. Was an organ donation realised?

Yes **No**

Refusal by family members

Deceased made his will known orally

Deceased made his will known in writing (e.g. donor identification)

Circulatory failure after determination of brain death

No release by the prosecutor

Other reasons \_\_\_\_\_

Recorded by Name \_\_\_\_\_ Function \_\_\_\_\_ Date \_\_\_\_\_

**Figure 1** Data entry form for deceased with primary or secondary brain damage in the intensive care unit.

organ donation had been given. *Effective organ donor* is the definition for donors from whom at least one organ had been removed and been found to be suitable for transplantation. So-called *utilized donors* were those from whom at least one organ removed had been transplanted. The *conversion rate* is the percentage of effective organ donors arising from the potential donors.

## Results

A total of 2019 deceased with primary or secondary brain damage were evaluated (Table 2). This is equivalent to 65.6 deceased p.m.p. and year.

The causes of the primary or secondary brain damage in order of frequency were: nontraumatic intracranial haemorrhage (51%), craniocerebral injury (22.1%), ischaemia (11.9%) and hypoxic damage (10.4%), brain tumor (1.6%), inflammatory disease of the brain (1.5%) and in 1.6%, other diagnoses. When the medical contraindications ( $n = 196$ ) in the data entry form were subtracted, 1823 possible organ donors (59.2 p.m.p./year) resulted.

About 538 patients who were medically suitable for organ donation died due to sudden and unexpected circulatory failure or as a result of therapy reduction because of

the infaust prognosis associated with the primary disease. 1285 potential organ donors (41.8 p.m.p./year) could thereby be identified during the time frame of the study.

Sixty-four percent of the deceased reported were potential organ donors. The conversion rate (conversion of potential into effective organ donors) was 47%. The circumstances that negatively affected the conversion rate in order of frequency were: refusal by family members (72.5%), circulatory failure during or after finalisation of the diagnosis of brain death (16.9%), and other factors (10.6%). The latter means that, e.g. no relative could be contacted, the identity of the deceased could not be determined, or the question of organ donation was unacceptable (question was not posed because in the opinion of the physician, talking with the family members was not possible as they were in an emotionally exceptional state that did not allow a conversation). 'Other factors' also comprise cases with lacking consent from the public prosecutor, or cases in which rapid section showed histological organ or malignant disease after a former curatively treated malignant disease (malignant disease with varied degrees of recurrence).

A total of 47.2% of the potential donors were converted to effective organ donors during the time frame of

	2002	2003	2004	2005	2002–2005
Deceased in ICU with brain damage*	479	493	531	516	2019
Number per million persons/year	62.05	63.94	69.14	67.28	65.60
Med. contraindications from question 11	60	48	44	44	196
Possible organ donors	419	445	487	472	1823
Number per million persons/year	54.28	57.72	63.41	61.54	59.24
Circulatory failure from question 12 (Fig. 1)	125	139	146	128	538
Potential organ donors	294	306	341	344	1285
Number per million persons/year	38.08	39.69	44.40	44.85	41.76
Circulatory failure during the observation time	27	25	18	15	85
Circulatory failure after completion of brain death diagnosis	4	5	5	4	18
Relatives could not be contacted/identity of the donor could not be ascertained	9	3	4	5	21
Questioning of the relatives unacceptable	2	2	4	5	13
No public prosecutor consent	1				1
Refusal by relatives	94	123	146	129	492
Donors with consent	157	148	164	186	655
Number per million persons/year	20.34	19.20	21.35	24.25	21.29
Number of donors lost in ICU	5	5	6	8	24
Number of donors from whom no organ was taken in the OR	4	1	13	7	25
Conversion rate (%)	50.3	46.4	42.5	49.7	47.2
Effective organ donors	148	142	145	171	606
Number per million persons/year	19.17	18.42	18.88	22.29	19.69
Number of donors from whom no organ was transplanted		3	1	2	6
Utilized organ donors	148	139	144	169	600
Number per million persons/year	19.17	18.03	18.75	22.03	19.50

\*In north-east donor region of Germany.

**Table 2.** Experimental results from deceased with primary or secondary brain damage\* during the years 2002–2005.

**Table 3.** Selected parameters for the characterisation of the deceased, possible donors, potential donors, effective donors, and consented donors for organ donation during the years 2002–2005.

	Age (years) (mean ± SD) min. (months)/max. (years)	Days in ICU [days] (mean ± SD) min./max.	Brain damage atraumatic/traumatic	Sex male/female
Deceased	55.7 ± 18.5 3/98	5.4 ± 6.0 1/68	1582/437 (78%/22%)	1119/900 (55%/45%)
Possible organ donors	55.1 ± 18.5 3/98	5.2 ± 5.4 1/56	1414/409 (78%/22%)	1008/815 (55%/45%)
Potential organ donors	52.2 ± 18.2 3/92	5.0 ± 5.2 1/43	999/286 (80%/20%)	713/572 (55%/45%)
Donors with consent	50.5 ± 17.8 3/89	4.9 ± 4.3 1/42	496/159 (76%/24%)	370/285 (56%/44%)
Effective organ donors	49.7 ± 17.9 3/89	4.9 ± 4.4 1/42	447/153 (74%/26%)	340/260 (57%/43%)

the investigation, and 99% of the effective donors were converted to utilized donors. The reasons why 1% of the organs taken could not be transplanted were organ and malignant diseases ( $n = 6$ ) which were detected by histological examination in the receiving transplantation centres (Table 2).

The mean age of the deceased as a whole during the time frame of the investigation was 55.7 years, that of potential donors was 55.1 years, and of consented organ donors was 50.5 years. The average amount of time spent in the ICU was 5 days for the three groups; 80% of the brain damage was of nontraumatic origin and 55% of deceased were male (Table 3).

A total of 828 (41%) of all deceased were in the age group 16–54 years and 760 (38%) were in the age group ≥65 years. In the 16–54 year age group, 7% of the deceased exhibited medical contraindications; in the

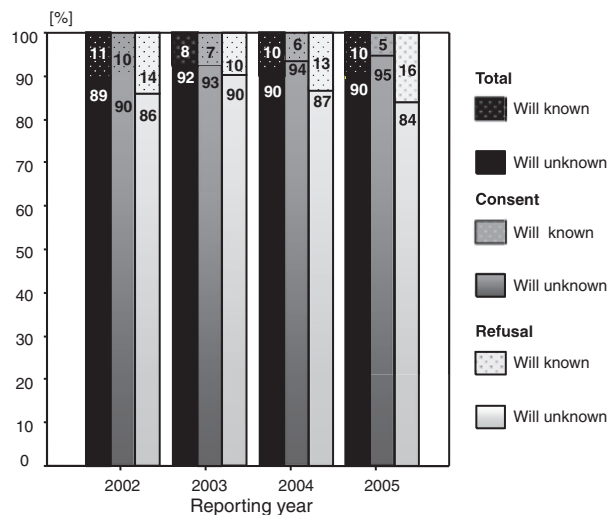
age group ≥65 years, it was higher (12%) as expected. 74% of the deceased in the age group 16–54 years were identified as potential organ donors; the proportion in the age group ≥65 years was 49.6%. In addition to the more frequent medical contraindications, the reasons for this difference were the twice as frequent number of cases of sudden and unexpected circulatory failure during treatment or after therapy reduction in cases of inf-aust prognosis of the primary disease in the ≥65 year age group. During the investigation period, consent for organ donation could be obtained for 58% of potential donors in the 16–54 year age group, while in the age group ≥65 years, it was only 43.5%. The reasons for this were the higher percentage of refusals (42.7%) and circulatory failure during the observation time and after finalisation of the diagnosis of brain death (11.2%) (Table 4).

**Table 4.** Number of deceased, possible, potential, and consented donors during the years 2002–2005 broken down into four age groups.

	≤15 years	16–54 years	55–64 years	≥65 years
Deceased	53 (100%)	828 (100%)	373 (100%)	760 (100%)
Possible organ donors	50 (94.3%)	770 (93%)	334 (89.5%)	669 (88.0%)
Potential organ donors	44 (83%)	615 (74.3%)	249 (66.8%)	377 (49.6%)
	100%	100%	100%	100%
Circulatory failure during or after the diagnosis of brain death	4 9.1%	35 5.7%	22 8.8%	42 11.2%
Relatives could not be contacted/identity of the donor could not be ascertained		11 1.8%	4 1.6%	6 1.6%
Questioning of the relatives unacceptable	4 9.1%	4 0.7%	2 0.8%	3 0.8%
No public prosecutor consent				1 0.3%
Refusal by relatives	17 38.6%	208 33.8%	106 42.6%	161 42.7%
Donors with consent	19 43.2%	357 58%	115 46.2%	164 43.5%
Effective organ donors	19 (3.1%) 43.2%	339 (55.9%) 55.1%	106 (17.5%) 42.5%	142 (23.5%) 37.7%

	University hospitals	Hospitals with neurosurgery	Hospitals without neurosurgery
Number of potential organ donors	413 (32%)	599 (47%)	273 (21%)
	100%	100%	100%
Number of refusals	162	230	100
	39.2%	38.4%	36.7%
Circulatory failure during or after the diagnosis of brain death	37	44	22
	9.0%	7.3%	8.0%
Relatives could not be contacted/identity of the donor could not be ascertained	7	12	2
	1.7%	2.0%	0.7%
Questioning of the relatives unacceptable	5	5	3
	1.2%	0.8%	1.1%
No public prosecutor consent		1	
		0.2%	
Number of donors with consent	202	307	146
	48.9%	51.3%	53.5%

**Table 5.** Factors that have an effect on the conversion rate, subdivided into three hospital groups during the years 2002–2005.



**Figure 2** Will of the deceased known or not known by the relatives with regard to consent and refusal of organ donation.

Thirty-two percent of the potential organ donors were identified in the three university hospitals, 47% in the hospitals with neurosurgical departments, and 21% in the 119 hospitals without neurosurgical departments. The percentage of consented donors of the number of potential organ donors was 53.5% in the hospitals without neurosurgical departments, which was higher than in the university hospitals (48.9%) and the hospitals with neurosurgical departments (51.3%). The main reason for this was the lower number of refusals (Table 5).

Figure 2 refers to the conversations with the next of kin conducted for acute cases during the years 2001–2005 and shows that approximately 90% of relatives did not know what decision the deceased had made while still alive. These numbers contradict the results of the representative 2001 forsa survey which ascertained the willing-

ness for organ donation after one's own death of 67% of those asked throughout the country, and in the states of Berlin, Brandenburg, and Mecklenburg-Western Pomerania, 62 to 65% (Fig. 3).

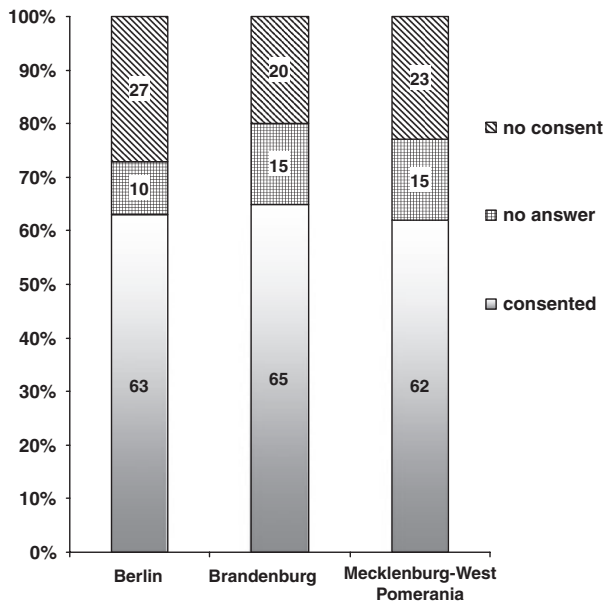
## Discussion

The number of potential organ donors is based on extrapolation, whose basis is retrospective data collection in hospitals, usually carried out by external experts. The comparability of study results is problematic as inclusion and classification criteria of the deceased, the medical contraindications, and the donor definitions are not uniform. Thus, many studies in the USA have included only deceased with no medical contraindications to organ donation up to the age of 70 years, while a Spanish study did not take medical contraindications into account [5–7].

The method that we used ensured continuous and prompt collection of data without being very time-consuming for the hospitals. The prerequisite was, however, that the hospital management and the physicians working on the ICUs regarded the reporting of the deceased as an important internal quality control tool for organ donation and that the DSO staff made intensive efforts to ensure that data was returned and to check the plausibility of the data submitted.

Further advantages were that only deceased with primary or secondary brain damage could be included and grouped as potential organ donors if they had no medical contraindications to organ donation and if brain death diagnostics (coma, loss of brainstem reflexes, apnoea) had been started or conducted according to the recommendations of the German Medical Association [8].

The disadvantage was that only those data entry forms that were returned could be evaluated so that, without



**Figure 3** Answers to the questions: Would you agree in principle to have organs removed after your death, or would you not be in agreement? [14].

further follow-up, DSO could not be certain that all relevant deceased had been reported. In our opinion, potential organ donors could also have been found amongst the more than 100 cases per year of sudden and unexpected circulatory failure or reduced treatment due to the infaust prognosis of the primary disease, particularly in the age group  $\geq 65$  years, if organ donation had been considered and the corresponding measures initiated.

The number of potential organ donors depends on a multitude of factors that vary from state to state and thereby make comparison between states difficult. Among these factors are: the collective mortality rate among patients with traumatic and atraumatic brain damage, the mortality rate of these patients in hospitals and in ICUs, the number of intensive care beds, the criteria for admission to ICUs, and the acceptance of organs from older donors by the transplantation centres.

The number of persons with primary or secondary brain damage dying in ICUs seems to be the major factor determining the size of the donor potential. In this study, the number of such deceased without age limitation between the years 2002–2005 was 66 p.m.p. and 41.8 were identified as potential donors. Approximately, 64% of deceased with the specified brain damage were potential organ donors. In the age group 15–54 years, this percentage was 74%, and in the age group  $\geq 65$  years it was only 49.6%. The reasons for the distinctly lower percentage of potential donors in this age group were the higher num-

ber of medical contraindications and twice the number of sudden and unexpected circulatory failures during treatment or following therapy reduction in cases of infaust prognosis for the primary disease.

In a study conducted in the United Kingdom (UK) over a two-year period, 4166 deceased with brain damage were recorded in 341 ICUs, of which 2740 were identified as potential donors. The number of deceased as well as the number of potential organ donors p.m.p. (35.3 and 23.2 respectively), were clearly less than the numbers we reported. Similar to our investigation, 66% of deceased with brain damage in the UK were potential organ donors [9].

Further studies must show whether the number of potential organ donors can be reliably concluded from the number of deceased with primary or secondary brain damage in ICUs.

Between the years 2002–2005, the mean age of actual donors was 49.7 years. It was higher in this study than the donor age in France and Spain (42.5 and 48.9 years respectively) during the year 2002 [4,7].

The conversion rate during the investigational period was 47.2%. It showed a definite age dependency. In the age group from 16 to 54 years, it was 55.1%, and in the age group  $\geq 65$ , it was 37.7%.

The main hindrance to the transformation of potential organ donors into effective organ donors was the refusal by relatives (78.1%). Noticeable is the significantly higher fraction of refusals ( $\chi^2$ ,  $P = 0.037$ ) obtained for potential donors in the age group  $\geq 55$  years (42.7%) in comparison to the age group 16–54 years (33.8%). The reasons for this have not been systematically investigated. Personal communication from hospital physicians and our own experience show that in the 55–64 and  $\geq 65$  years age groups, not only the spouse but also the children and grandchildren participate in the consent discussion, and a consensus amongst the relatives as to whether or not to consent – when the will of the deceased is not known – is often difficult and therefore the decision against organ donation prevails.

In the 119 hospitals without a neurosurgical department from which only 20% of potential donors were identified, the percentage of refusals based on the number of potential donors was 36.7%. In the university hospitals, it was 39.2% and in the hospitals with neurosurgical departments it was 38.4%.

As the number of conversations per physician is much lower in the smaller hospitals and the result with regard to organ donation consent is actually better than in the larger hospitals, the professionally competent, sensitive, and respectful discussion at the time of conveying the notice of death and the request for organ donation as well as the interactions with the family members at the

hospital seem to have a large influence on their decision.

The age group 16–54 years had 56% of the effective donors while the  $\geq 65$  age group had 23%. The large percentage of donors in the age group  $\geq 65$  years is due to the fact that in Germany there is no age limit for organ donation.

The statement made by Coppen *et al.* [10] that the ‘opt-out’ policy (presumed consent solution) is no guarantee of a high donor rate should be relativised in our opinion. The results of these investigations show that the number of potential donors is not dependent on legal regulation; however, the conversion rate (percentage of effective donors from the number of potential donors) certainly is. It is determined by the number of refusals and is clearly higher in the countries with an ‘opt-out’ policy than in countries with an ‘opt-in’ policy (informed/extended consent solution) [11–13].

The study also confirms the presumption that the largest potential for organ donors also exists in the university hospital and hospitals with neurosurgical departments. Therefore, intensifying collaboration with these hospitals is decisive for increasing organ donation, without neglecting the other hospitals.

The extensive clarification and the great willingness to donate organs on the part of the populace according to polls’ results are not reflected by more consents by family members for organ donation in the acute situation [14]. During the years 2002–2005, more than 90% of family members questioned in the north-east region did not know the wishes of the deceased. It seems to be the case that a positive attitude toward organ donation is neither documented by donor identification nor communicated within the family and thereby the decision lies with the relatives in acute situations. Approximately half of these relatives decided against organ donation. The reasons for refusing potential organ donations were no subject matter in this study. In Germany so far, it has not been investigated systematically why relatives consent to or decline an organ donation. Religious motives seem to be only marginally relevant [15].

Several studies confirm that it is easier for the family to consent to an organ donation if the wishes of the deceased are known and have been discussed in the family [16–19]. From our point of view integrating the issue of organ donation into schools’ curricula for pupils of 16 years or older is a decisive measure within the continuous efforts of public information and education. Thus, youths are enabled to make their own cognisant decisions and to broach the issue of organ donation in their family and among friends. Several studies of different countries show that young people are not only interested in and open minded about organ donation but that the knowledge and the discussion about

this issue with family members and friends have a positive influence on the attitudes toward organ donation [20–23].

From our point of view, an important measure for the continuous education of the population is the integration of the topic of organ donation and transplantation into the curriculum starting with the 10th school year, in order to provide pupils with comprehensive information and thereby enable an informed decision. In addition, introducing this topic to young people would create a greater awareness of this subject in the family than there has been to date.

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