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ORIGINAL ARTICLE

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Cost-benefit approach in evaluating investment into donor action: the German case

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Abstract Donor Action (DA) is an international initiative to help critical care units (CCUs) increase their own donation rates through improved-quality donation practices. Following a validated diagnostic review (DR), areas of weakness can be identified, and the appropriate changes introduced. Data gathered from a number of centers in nine European countries (including Germany) 1 year after the introduction of targeted improvement measures demonstrated a 59.2% ($P = 0.0015$) increase in donation rates. This analysis computes the cost-benefit thresholds of implementing the DA methodology from a German health–economic point of view, taking into account the treatment alternatives for end-stage renal disease (dialysis and transplantation) and comparing the DA program with current organ-donation practice. Lifetime direct medical costs and quality-adjusted life years (QALYs) were calculated for both arms, considering only changes in cadaveric renal transplantation rates. If DA leads to a 59% overall increase in organ donation in Germany, the program will result in 33 QALYs and 1.8-million euros cost savings per million population (PMP). Therefore, DA would be cost-effective below 2.66-million euros implementation cost PMP (or 218-million euros for the whole country). As the partial implementation cost of the program was far below the threshold, DA is more cost-effective than other publicly reimbursed medical intervention.

Keywords Organ donation · Quality assurance · Cost-benefit/cost-effectiveness analysis

Introduction

Management of end-stage renal disease (ESRD) by renal replacement therapy has advanced significantly over the past 2 decades [28]. Refinements in dialysis techniques combined with individualized drug therapy have allowed patients to be maintained in a state of reasonable health for 20 years or more. Advances in dialysis facilities, dialysis solutions, and dialyzers, increased knowledge of, and ability to manage, treatment-related complications have all, in varying degrees, contributed to the improved survival rates [6] of patients maintained on dialysis [3].

However, it is generally accepted that, compared with hemodialysis, renal transplantation is the more effective, and also the most cost-effective, therapeutic option for patients with ESRD, as it provides substantial benefits to quality of life [9, 10, 11, 19,27, 31] and patient survival [21, 23, 29] at reduced long-term costs [5, 8, 15, 16, 17, 20, 4]. The lower costs associated with transplantation have mainly been attributed to the cost difference between maintenance immunosuppression and routine dialysis. In addition, the higher morbidity associated with dialysis, plus the financial benefits of the improved productive capacity ('opportunity costs') of those patients who no longer require dialysis, are also factors to be taken into account [16]. However, the shortage of donor organs (living or cadaveric) is the most important factor limiting the number of patients with ESRD to whom transplantation can be offered.

The continued shortage of donor organs has led to the development at (inter)national, regional and local levels of a variety of organizational initiatives to increase donation performance. Experience in Europe and the US indicates that a consistent hospital protocol built on multidisciplinary consensus and teamwork can lead to a significant increase in donation. Such a protocol supports teamwork toward common goals: to identify all potential donors and provide optimal care for their relatives. It also cultivates a sense of institutional ownership of the donation process in participating hospitals and critical care units (CCUs). One such initiative is Donor Action (DA), an international collaboration that unites best practices to help hospitals increase donation rates through improved donation practices [37, 38].

Whilst DA is at various stages of implementation in different countries in Asia, Europe, North and South America, the number of centers and countries demonstrating immediate and significant effects of awareness is increasing and amounts to an overall increase of approximately 60% at 1 year following implementation. Sustained effects in centers with the longest follow-up promise a similarly encouraging long-term impact on donation rates as more countries implement this methodology [30].

Successful organ-donation programs such as DA require a substantial initial financial investment. Moreover, additional expenditures are necessary to maintain the program's initial momentum to effect sustained improvement in donation rates. While DA is available to countries at no cost, each country must make financial allowances for the training of appropriate personnel, adaptation of the program tools to national specifications, and the phased rollout into CCUs. A quality-assurance program such as DA can be considered a health-care intervention, which, in combination with kidney transplantation, yields a benefit in terms of quality of life and survival for patients with ESRD. Since it competes with other health-care interventions for public funding, its expected cost-effectiveness should be predicted before it is implemented at a national level. Our objective was to calculate those thresholds below which DA is cost effective in Germany. Cost effectiveness was defined as the program results in one quality-adjusted life year (QALY) at a cost below 25,000 euros. As national health authorities, social security departments and health-insurance companies (e.g., the German 'Krankenkassen') are increasingly concerned about the budget impact of health-care interventions, the long-term cost-saving threshold of DA was also calculated.

Materials and methods

DA program methodology

DA takes a systematic approach towards achieving quality assurance in donation [38]. The methodology is data based and designed to give hospitals participation and ownership in the development of improved donation practices that can be tailored to meet identified needs in CCUs. DA aims to streamline the roles of professional staff involved in the donation process and to focus the responsibility in the hands of dedicated and trained staff [30, 37]. The program provides a comprehensive package of tools, resources, and guidelines, to help diagnose a CCU's potential for donation, develop appropriate donation protocols, and establish a team with clearly defined roles and responsibilities in the donation procedure. In addition, it allows targeted and consistent education and performance-monitoring systems.

The process

1. Gaining hospital support. The first step is to gain support among senior hospital staff for the program. Such a group can form the basis of a permanent DA committee. In a second step, the committee informs appropriate colleagues about DA and clarifies its relevance for the workplace.
2. Performing the diagnostic review. The diagnostic review (DR) provides baseline information on a CCU's donation situation and has three components:
   - Retrospective medical record review (MMR). The MRR has been developed to measure gaps between potential and actual donors and to indicate when and where potential donors are lost. This retrospective MRR can establish a baseline against which improvements can be monitored.
   - Staff hospital-attitude survey (HAS). The staff HAS is an anonymous questionnaire, administered to medical and nursing staff in CCUs undergoing MRR, which assesses attitudes and knowledge about donation and transplantation, involvement, confidence and support in the donation process, and educational and training requirements.
   - DA system database. A software package has been developed that analyzes and reports on the findings from the MRR and HAS. The system features user-friendly screens for the entering of hospital data and a series of push-button reports which retrieve and analyze the data according to several pre-defined formats: raw figures, aggregated synthetic figures, and graphs. Data stored in the system can also be retrieved and analyzed with software packages such as Microsoft Access, Excel and Word. When reviewed with the MRR, the HAS database reports create a profile of the unit's donation practices.
3. Program tailoring. This is the bridge between analysis of the results of the DR and implementation of improvement measures in the CCUs. It is a way to adapt the program to meet the special needs of a CCU, based on the assessment of existing strengths and weaknesses provided by the results of the DR, and it too prioritizes areas for improvement of the donation process. The DR results are matched to the modules and an action plan is created. The core program modules can be adapted as necessary and introduced into the CCU, and the improvement program can be implemented.

4. Implementing the core program. The core program provides five modules that follow the donation process: donor detection, donor referral, family care and communication, donor maintenance, and organ retrieval. The modules contain tools, guidelines, and resources that help develop specific donation protocols that meet identified needs and come as 'tool kits' for daily use in CCUs. They can be used as sole tools or in any combination with others.
5. Monitoring and evaluating progress. DA is an on-going process that does not happen overnight. Once the initial DR has been analyzed, performance targets can be set. One can then use the database as a prospective monitoring tool by entering on-the-spot details of patients who die in CCU, and the data can be used for future analysis. With tools provided in the program modules, data are collected on an on-going basis so that progress can be constantly monitored.

Organ donation in Germany

On 1 January 2000, Germany's population amounted to 82.163-million inhabitants [14]. Similarly to international trends, the prevalence of ESRD in Germany has increased in recent years, leading to a constant growth in the number of patients undergoing dialysis treatment, from 42,950 (520 per million population; PMP) in 1996 to 44,858 (546 PMP) in 1999. In 1999 alone, 12,137 new patients with ESRD were registered [26]. However, the renal transplantation rate has not grown to the same extent.

The number of donors PMP in Germany has remained around 12.9 during recent years, with a maximum of 13.8 in 1993, and a minimum of 12.2 donors PMP in 1994 [7]. This average donation rate PMP is far below the 1999 value for Spain (33.6 donors PMP), Austria (25.9 donors PMP) or Belgium (25.2 donors PMP). Austria and Belgium are two countries with socio-economic standards and demographics comparable to those in Germany, and share the same medical donation and transplantation standards of practice within the Eurotransplant organization. Although the current concept of 'donors PMP' as an accurate predictor of a country's true potential for donation is under dispute [1], it is beyond doubt that the 160% difference in donation rates between countries such as Spain and Germany suggests considerable room for improvement. Recent MRR data collected by the Deutsche Stiftung Organtransplantation (DSO) in 143 hospitals in Bavaria over a period of 5 months demonstrated that from a total of 214 brain-dead and medically suitable potential donors, only 32% were realized. The main causes for missed donations were donor identification and maintenance problems (24%), and refusal to give consent to donation by the next of kin (44%; D. Boesebeck (2001); personal communication).

In Germany, the average yield of kidneys retrieved per donor and considered suitable for transplantation has decreased slightly from 1.92 in 1992 to 1.86 in recent years. It is presumed that this decrease is due to an increase in the average donor age, from 37 years in 1992 to 45 years in 1999. As 36% of the donors in 1999 were older than 54, they are less likely to be suitable for heart, lung or pancreas donation [26]. Fortunately, and despite a decrease in kidney donation, a positive tendency has been observed towards extra-renal organ retrieval, which rose from 57% to 74% during the same observation period, totaling an average of 3.18 organs/donor in 1999.

Overview of the economic model

As DA results in more donors and thus more transplants for patients on the waiting list, we aimed to develop a cost-effectiveness model that takes into account the specific character of ESRD and the therapeutic options that are currently available. To avoid unrealistic and simplified assumptions as required by conventional decision trees, we decided to use a Markov model to compare cadaveric kidney transplantation with dialysis of those patients selected for transplantation but remaining on a transplant waiting list. [34].

In this analysis, the length of a Markov cycle was 1 year. The scope of the base case analysis was 20 years. Within this period, treatment costs and quality-adjusted life years (QALYs) were calculated for patients treated with the two renal replacement options. Half-cycle correction was used for both costs and QALYs.

Transition probabilities for graft half-life and patient survival were calculated, based upon graft survival and half-life data from the published literature. Cadaveric graft survival at 1 and 3 years post-transplant was assumed to be 83.2% and 72.1%, based on German data of Eurotransplant (G.G. Persijn (2001) Eurotransplant; personal communication), while graft half-life is 13.8 years, based on United Network for Organ Sharing (UNOS) data [12]. These values are not censored for death with a functioning graft. The proportion of patients who died with a functioning graft was assumed to be between 25.3 and 31.5% [33].

Based on a USRDS cohort [39] the projected life expectancy for patients on waiting lists for dialysis and transplantation was assumed to be 10 and 20 years, respectively. This multivariate retrospective analysis accounted for the effect of major confounding factors, such as age, gender, race and cause of ESRD.

Survival rates of the patients at 1 and 5 years after graft loss were 76% and 48%, respectively [22]. Utility values were derived from the most recent German analysis [25]. Waiting on dialysis results in 0.76 utilities. Renal transplantation leads to 0.83 utilities during the first year post-transplant, and 0.88 thereafter.

The annual direct medical cost of a patient on dialysis is 44,250 euros [18]. Cadaveric kidney transplantation costs 51,130 euros [2] initially, and in the maintenance phase 10,230 euros annually. The cost of transplant nephrectomy was assumed to be 1,510 euros [2]. We assumed that the willingness to pay for a QALY gain was 25,000 euros. The applied discount factor was 5% for both QALYs and costs [25]. The economic impact of the program on increased availability of other organs for transplantation was not considered in this analysis.

Results

A waiting period on dialysis of over 20 years yields 5.97 QALYs after discounting. Cadaveric kidney transplantation results in 8.39 QALYs, which is a 2.42-QALY increase when compared with dialysis. The cumulative discounted treatment costs per patients are 347,737 and 215,211 euros for waiting on dialysis and transplantation, respectively, resulting in a difference of 132,526 euros.

Figure 1 shows how cost savings and rising QALYs due to transplantation change over time. Transplantation is an investment that reaches the break-even point at year 2. Subsequently, it results in increasing QALYs and cost savings, with time. The plateau of cost savings is at 25 years. The economic value of a health-care intervention can be calculated by adding the value of health benefits to the potential cost savings. The health benefit is expressed in QALY terms, which can be converted to monetary terms by using a willingness-to-pay conversion rate. Therefore the economic value of 2.42

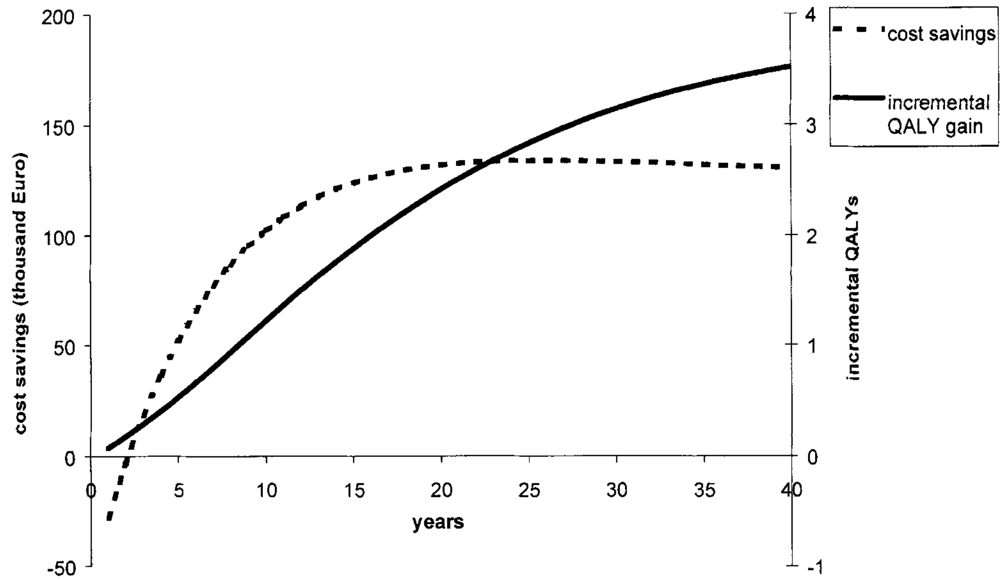

Fig. 1 Cost-savings and QALYs gained per transplant patient compared with waiting on dialysis

Table 1 Survival gain advantage of dialysis vs cadaveric transplantation

Assumption	Cadaveric graft survival at 1 year (%)	Cadaveric graft survival at 3 years (%)	Survival on dialysis, waiting listed Years	Incremental QALY gain per transplant patient	Incremental cost-savings per transplant patient (×1,000 euros)	Cost-effectiveness threshold PMP (×1,000 euros)
Impact of patient survival on dialysis raises the cost-effectiveness threshold for DA (PMP)						
Base case	83.20	72.10	10	2.47	127.3	2,602
Survival of waiting listed dialysis increases	83.20	72.10	15	1.47	184.1	3,041
Impact of cadaveric graft survival on the cost-effectiveness threshold for DA (PMP)						
Base case	83.20	72.10	10	2.47	127.3	2,602
Graft survival in Germany matches Eurotransplant average	84.70	75.4	10	2.58	127.1	2,639
Graft survival in Germany matches UNOS average	89.40	76.3	10	2.65	127.5	2,666

QALYs is 60,512 euros (25,000 euros ×2.42). If we add this amount to the net present value of cost savings, the economic value per incremental kidney gained is 193,039 euros over 20 years.

If organ donation increased by one additional donor PMP throughout Germany, this would lead to 370 QALYs gained and cost savings of 20.3-million euros. If DA were as effective in Germany as in other European countries, the program's implementation would increase donation rates by 59%, or from 12.5 donors PMP to 19.9 donors PMP. Consequently, a 59% increase in donation rates would result in cost savings of 1.8-million euros and a QALY gain of 33 PMP. In the event of a nation-wide implementation of DA, these values would amount to 150-million euros and 2,737 QALYs for the whole country. Therefore, implementation of DA should be considered cost effective below 2.66-million euros PMP, or 218-million euros for the whole country.

Sensitivity analyses

The survival gain advantage of cadaveric transplantation over dialysis does not have a significant impact on the cost-effectiveness thresholds, as shown in Table 1. If we assume that the average survival time of patients on dialysis increases from 10 to 15 years, the QALY gain due to DA is reduced, but the cost savings are increased. If cadaveric-graft survival rates in Germany improve to match Eurotransplant (G.G. Persijn (2001) Eurotransplant; personal communication) or UNOS [35] averages, QALY gains will slightly improve.

The time scale of the analysis, and therefore the number of Markov cycles, has a strong impact on the cost-effectiveness threshold of DA. The cost-effectiveness threshold of DA increases over time. However, a 20-year time scale already gives a good estimate on the lifetime cost effectiveness of DA, as the slope of the threshold curve decreases significantly after 20 years.

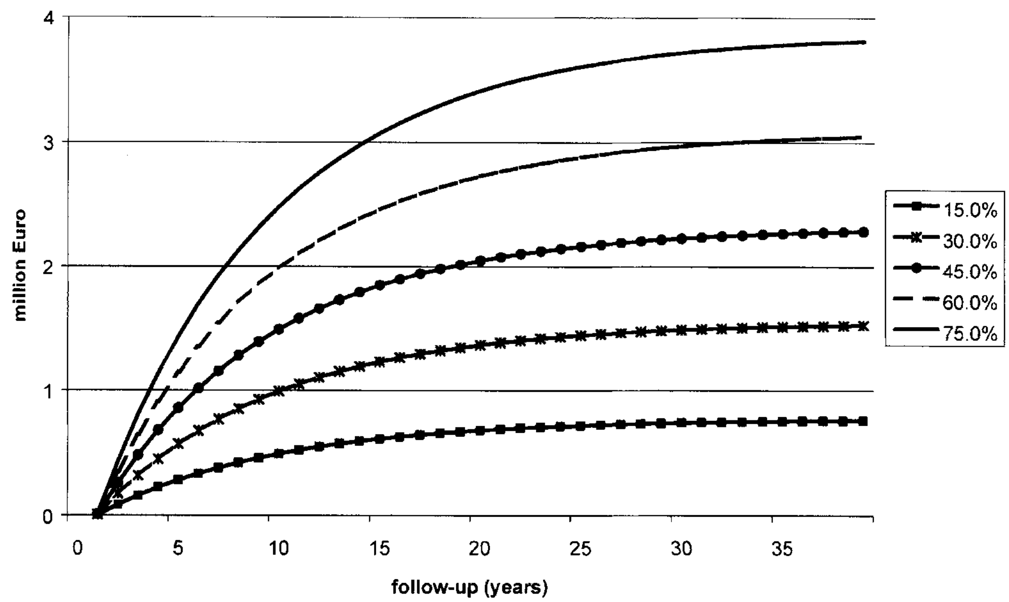

Fig. 2 Bivariate sensitivity analysis—impact of DA success rate and the time scale of the analysis on the cost-effectiveness threshold of DA (PMP)

This sensitivity analysis shows that increasing the scope of the analysis beyond 20 years does not add too much value.

The cost-effectiveness threshold of DA also varies, depending on the success rate of DA. If its success rate in Germany is only 15% instead of the 59.2% overall increase that is currently reported from European centers, the cost-effectiveness threshold of DA will need to be reduced from 2.66-million euros to 664,000 euros PMP. However, such an investment will still vastly exceed the amount spent on DA in pilot centers so far. Figure 2 shows a bivariate sensitivity analysis, depicting the impact of success rate and the time scale of the analysis on the cost-effectiveness threshold of DA.

Dialysis, which is assumed to be 100% reimbursed by national health services, provides a QALY gain at a price of 58,224 euros (see 44,250 euros per 0.76 QALYs). Therefore, the figure of 25,000 euros for a QALY gain is a conservative willingness-to-pay estimate. If 58,224 euros as the willingness-to-pay conversion rate is used, the cost-effectiveness threshold will increase from 2.66 to 3.76-million euros PMP.

Discussion

Initial results indicate that DA yields substantial cost savings and QALY gains at substantially lower implementation costs than the calculated threshold. If the total cost of implementing DA in Germany is fewer than 2.66-million euros PMP (or 218-million euros for the entire country), and if the program results in a 59.2% increase in organ donation, then, based on conservative estimates, DA will be far more cost effective than other currently reimbursed medical interventions (including dialysis). Consequently, DA should be publicly funded. Even below a 1.82-million euro PMP implementation cost, the program will be cost saving.

However, there are a few notable limitations that should be considered in the interpretation of the results of this economic model. We utilized the perspective of the third-party payer (national health services), and not that of society as such; furthermore, we did not account for indirect or direct costs incurred by the patient.

If extra-renal organ transplants are also cost effective, other transplants will further increase the cost-effectiveness potential (extra QALYs gained) of DA at zero cost. As there is already evidence on the cost effectiveness of liver [24, 25], heart [32], kidney–pancreas [13] and lung [36] transplantation, taking only kidney transplantation into account when calculating the cost-effectiveness threshold for DA is a highly conservative approach. Incorporating economic consequences of other organ transplants into the analysis will further improve cost-benefits of DA when compared with current practice.

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