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* National working group Informed Consent Live Kidney Donation

Keywords
- Informed consent
- Live donor nephrectomy
- Complications
- Donor education
- Donor comprehension

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ABSTRACT

Introduction Informed consent is mandatory for every (surgical) procedure, but is even more important when it comes to living kidney donors, undergoing surgery for the benefit of others. Donor education, leading to informed consent, needs to be carried out according to certain standards. Currently, informed consent procedures for live donor nephrectomy vary per center and even per individual healthcare professional. By assessing what information donors need, and want to hear to prepare them for the operation and convalescence, the basis for a standardized, uniform surgical informed consent procedure for live donor nephrectomy can be created.

Methods and analysis The PRINCE project is a prospective, multicenter cohort study, carried out in all eight Dutch kidney transplant centers. Donor comprehension of the live donor nephrectomy procedure and postoperative course will be evaluated by means of pop quizzes. A baseline cohort (prior to receiving any information from a member of the transplant team in one of the transplant centers) will be compared to a control group, who receive the pop quiz on the day of admission for donor nephrectomy. Donor satisfaction will be evaluated for the last group. The primary endpoint is donor comprehension. In addition, those elements that have to be included in the standardized formant informed consent procedure will be identified. Secondary endpoints are donor satisfaction, current informed consent practices in the different transplant centers, and correlation of donor comprehension with surgeons’ estimation thereof.

Ethics and dissemination Approval for this study was obtained from the medical ethical committee of the Erasmus MC, University Medical Center, Rotterdam on February 18th 2015. Secondary approval has been obtained from the local ethics committees in six of the other seven participating centers. Approval in the last center has been requested. Results will be published in a scientific journal.
Registration NTR5374

Strengths and limitations of this study

Strengths:

• Unique in topic and design
• National study
• Large cohorts

Limitations:

• Use of unvalidated questionnaires

INTRODUCTION
The Netherlands have a leading role when it comes to live kidney donation (31 living donors per million of population[1]), with more than half of all kidney transplants involving a living donor. In 2013, 520 live donor nephrectomies were performed out of a total of 954 kidney transplantations (55%)[2]. One of the most successful paired kidney exchange (PKE) programs have been created in the Netherlands[3, 4], and many trials assessing the surgical procedure for the live donor nephrectomy have been initiated here[5-8]. With very low complication and mortality rates, live donor nephrectomy is a safe, low-risk elective surgical procedure. In contrast to patients, living donors are (generally) healthy individuals from whom an organ is removed for the benefit of others. It is of the utmost importance that any patient is correctly informed about the specific details, risks and alternatives of a procedure, but the unique character of the live donor nephrectomy may warrant an extra vigilant approach to the informed consent process.

Relevance further increases since extended criteria donors (e.g. overweight/obese donors, older donors, donors with hypertension and/or vascular multiplicity/anomalies) are increasingly being accepted[9]. These individuals could be more prone to complications, and potential donors must be well aware of the risks involved with their upcoming procedure, as well as future perspectives with only one kidney. These donors go through numerous steps during the informed consent procedure. In most Dutch centers, they are first seen by a nephrologist, transplant coordinator or nurse practitioner, who provide a lot of information about the donation procedure. In addition, most are seen by a social worker and some by a psychologist. The last person in the chain of information provision is usually the surgeon, who is responsible for performing the donor nephrectomy. The relevance of uniform information provision is further underlined by paired exchange procedures, which are more frequently employed these days. It is not uncommon in the Netherlands that donors receive their education/information in one center but surgery in another. They may receive different information in these centers, which may be confusing. The Dutch situation is herein quite unique and stands in contrast to PKE programs in some other countries where the donor and recipient both remain in their own
centers but the donor organ is transported[3, 4]. It is therefore mandatory that the Dutch transplant centers adopt a standardized, uniform informed consent procedure. But even if donors do not travel between centers, as is the case in many other countries, medical professionals as well as donors will still benefit greatly from a standardized format.

The question remains what this standardized format should comprise. The living donor nephrectomy itself has become fully implemented in the general practice and much more information has become available regarding outcome and possible peri- and postoperative complications (Kortram et al., submitted). Due to these developments living kidney donation has gained ground over the past decades, and numbers are increasing worldwide. This merits a revisited opinion on information disclosure and consent. Although the informed consent process has evolved alongside the surgical procedure in an attempt to incorporate the most up to date knowledge and transfer it to potential donors in an understandable fashion, it has yet to be brought to perfection[10].

Every physician, ethicist or legalist will agree that a person giving consent should be “fully informed”, “free of coercion” and “competent”[11], but there is no consensus on details to be provided during the process, nor the manner in which these should be delivered. There are many different policies and guidelines outlining matters that should be disclosed to potential donors, but details are often not specified[12, 13]. These differences make it impossible for healthcare professionals to practice a uniform strategy and it is challenging to determine which patient has received which information. Recent data demonstrate that when tested on their knowledge, a large number of living kidney donors underestimate the complications and risks of living donor nephrectomy[14]. Surman et al. published similar findings in renal and liver transplant patients, revealing significant conceptual limitations to their knowledge about their postoperative situation, underlining the importance of adequate preoperative education[15].

Recently, a study performed by Gordon et al. was published regarding informed consent in
living liver donors, again demonstrating that a large number of donors report a lack of understanding of the provided information (40%)[16]. Comparable results are demonstrated in other studies, where donors report varying degrees of (dis)satisfaction with and misunderstanding of provided information[17-19]. The question is raised whether the necessary information has not been provided correctly, whether donors simply not understand or remember it, or, as has been proposed by some, whether they selectively filter information and thus miss particular risks associated with donation[20-22]. Standardizing the informed consent procedure will help us better understand and address this.

Pilot study

A pilot study was performed (Kortram et al, submitted), preoperative surgical outpatient clinic visits of 46 potential living kidney donors were observed and provided information was scored. Immediately after giving consent for donor nephrectomy, and again on the day of admission for the operation, donors received a questionnaire testing their knowledge of the upcoming operation. They received an evaluation questionnaire regarding their satisfaction with and understanding of the informed consent procedure 6-12 weeks postoperatively. After completion of the pilot study, pop quiz questions were rephrased where necessary, and the scoring system was adjusted.

Survey

A web-based survey was created to assess the current situation in the eight Dutch transplant centers (Kortram et al, submitted). All surgeons who were possibly involved, or had been so in the past, in live kidney donation were invited to complete the survey (n=50). The response rate was 98% (N=49, of which 32 were still active in living donor education). Respondents were asked which complications they discussed with potential donors during the informed consent process for live donor nephrectomy. Important complications were not always disclosed:
bleeding was the only complication every surgeon mentioned. Risk of death was always
mentioned by 16 surgeons (50%), sometimes by 12 (37.5%), and four surgeons (12.5%) never
disclosed this disastrous complication. Thus, some improvements can be made regarding
information provision.

METHODS AND ANALYSIS

Design

The PRINCE (Process of Informed Consent Evaluation) Inventory project is designed as a
prospective, multicenter cohort study. The study is conducted in the eight Dutch kidney
transplant centers, which are all University Medical Centers (to which transplantation is
confined).

The study is divided into two parts: a cross-sectional study (Cohorts 1 & 3) and a longitudinal
study (Cohort 2). Both parts are prospective studies.

The cross-sectional study comprises pop-quizzing two cohorts of donors at different stages
during the pre-donation period. The cross-sectional design is chosen to include as many donors
as possible. Cohort 1 will be included when the potential donors first present themselves to the
hospital, at the outpatient nephrology clinic, prior to having spoken to any member of the
transplant team. The second group will be included one day preoperatively on admission for
donor nephrectomy (Cohort 3). These donors will have received all information possible from
different members of the transplant team.

Both groups of donors will be asked to fill out a pop quiz regarding their knowledge of the donor
nephrectomy procedure, the possible short- and long-term complications and details about
hospital admission and convalescence. The second group of donors will receive an additional
questionnaire three months after surgery to assess their satisfaction with the educational- and informed consent procedure retrospectively.

The donors included in the longitudinal part of the study, i.e. Cohort 2, will be followed more closely to obtain a detailed conception of the informed consent process in the eight different centers. The donors that are eligible for inclusion in Cohort 2 are those donors already included in Cohort 1, that are being referred to the surgical outpatient clinic. This will mainly be influenced by their recipient's status (preemptive, comorbidity etc.), and whether the donor has been approved by the nephrologist. The surgical consult will be recorded (audio only). These recordings will be analyzed using a standardized checklist, to assess which complications and other details are specifically disclosed by the surgeon. Donors in this cohort will be asked to fill out the same pop quiz as the first cohort, immediately after the surgical consult and again on the day of admission. They will also receive the evaluation questionnaire three months after surgery.

Objectives

Primary Objectives:

The primary objectives of this inventory project are:

1. To assess donor comprehension of all aspects of the donation procedure during different stages of information provision;
2. To assess whether the information provided to (potential) living kidney donors in the Dutch kidney transplant centers is sufficient and provided in the best possible manner;
3. To assess which elements have to be included in the donor education program (this will be based on our medical opinion in combination with the data provided by included donors);
4. To create a uniform, standardized informed consent procedure for the live donor nephrectomy, to be implemented in all Dutch kidney transplant centers.

Secondary Objectives:

The secondary objectives of this inventory project are:

1. To compare informed consent procedures and donor education between the different Dutch transplant centers.

2. To assess whether living donors feel prepared for surgery and are satisfied with the informed consent procedure.

3. To assess whether donor comprehension actually concurs with surgeons' perception of what they believe donors understand.

Study population

The study population is divided into three cohorts. Cohort 1 comprises all potential living kidney donors that are seen at the outpatient nephrology clinic. Exclusion criteria for this cohort are: inability to understand the Dutch language, prior donation education in a kidney transplant center, age < 18 years and a mental illness prohibiting informed consent. Cohort 2 is obtained from a random sample of referred Cohort 1 donors. Cohort 3 comprises all donors that are admitted to the surgical ward for live donor nephrectomy. Exclusion criteria for the latter two cohorts are: inability to understand the Dutch language, age < 18 years, and a mental illness prohibiting informed consent.

Sample size calculation

Since this study is an inventory project, making a comparison of informative findings rather than performing one specific measurement, a sample size calculation is not applicable.
The total number of live donor nephrectomies differs between the eight centers (figure 1), and it is therefore unrealistic to set the same goal for every center. But it is necessary that all participating centers provide a large enough number of subjects, seen by preferably all, but at least a number of different members of the transplant team to eliminate, as much as possible, inter-observer and timing-related variations in donor education. The following inclusion aims are set: 400 donors for cohort 1 (50 donors in each center), 80 for cohort 2 (10 donors in each center) and 200 for cohort 3 (Number of donors per center calculated based on procedures performed in 2014).

Figure 1. Number of live donor nephrectomies per center in 2014

Primary & Secondary endpoints

The first main study parameter is donor comprehension of the donation procedure. This will be assessed by means of a pop quiz score. Scores will be compared between the different cohorts and/or time-intervals. The elements to be included in the standardized informed consent format comprise the second main study parameter. These items will be assessed by different means. Obviously, some items will have to be included, based on the knowledge we already have from experience and the currently available literature (Kortram et al., submitted). The audio recordings of the Cohort 2 donors will provide us with information about the currently disclosed
items in each center. We will try to correlate this to donor comprehension of the individual items on our checklist. In addition, all Cohort 3 donors receive an evaluation questionnaire in which they are asked whether they’ve missed anything during the informational process.

The first secondary study parameter is the manner of obtaining informed consent and the contents hereof in the eight Dutch transplant centers. This parameter is a descriptive parameter, which cannot be directly measured. Some aspects of the process itself will be collected and compared between centers: e.g. the location where donors are seen (outpatient clinic, ward), the manner of obtaining consent (assumed, verbal, written), and who is responsible for obtaining consent (surgeon, nephrologist). These procedures will be compared to create the optimal format for all Dutch centers. Satisfaction will be measured using the visual analogue scale (VAS-score, 0-10) in addition to describing questions. The last secondary parameter that will be assessed is the correlation between the donor’s comprehension and the surgeon’s estimate thereof. Surgeons will be asked to “predict” their donor’s score after the consultation, using a 0-10 scale, 0 meaning no comprehension whatsoever and 10 meaning perfect reproduction of all details. This will be correlated to the donor’s pop quiz scores.

Data collection & follow-up

Each donor will receive an anonymous study number, which will be used for the database. All subjects will be asked to fill out one or more, with a maximum of three pop quizzes. Donors included in cohort 3 will also be sent an evaluation questionnaire three months postoperatively. In addition, every donor is asked to fill out a baseline questionnaire with general questions regarding social economic status, religion and donation activities. The random sample of donors that will be followed longitudinally will be monitored more closely. The preoperative surgical consult at the outpatient clinic will be recorded (audio only), and these consults will be scored using a standardized checklist. These donors will receive one additional pop quiz immediately
after the surgical consult. All other tests and procedures will be according to local protocol for
the screening and treatment of living kidney donors.

**Statistical Analyses**

Statistical analysis will be performed using SPSS version 21 and R version 3.1.2. Dichotomous
data and counts will be presented in frequencies. Continuous data will be presented in means
with a standard deviation (SD) or median value with a range. In addition, some information will
be presented in a literal descriptive fashion (i.e. specific answers to the pop-quiz questions).

Differences between scores will be compared by the independent sample t-test, the pairwise
comparison t-test or One-Way ANOVA. To compare differences in mentioning frequencies of
individual complications between Cohort 1 and Cohort 3, Chi\(^2\) tests will be performed. For the
donors in Cohort 2 the McNemar test will be performed to compare individual mentioning
frequencies at the different time intervals. The McNemar test compares the number of those
who first scored positive and then negative with the number who first scored negative and then
positive: if these numbers differ significantly from each other an increase or decrease can be
concluded. A p-value of <0.05 will be considered statistically significant. Multivariate analysis
will be performed using linear regression. If necessary bootstrapping will be applied.

**Feasibility**

Approval from the medical ethical committee for the PRINCE project was obtained on February
8\(^{th}\) 2015, and the first donor was included on March 30\(^{th}\) 2015. At this moment approval of local
ethical committees has been obtained in six of seven of the other participating centers, and
donors are being included in the different cohorts in these centers. In the last center, approval
from the local ethics committee has been requested.
ETHICS AND DISSEMINATION

Ethics

Approval for this study was obtained from the medical ethical committee of the Erasmus MC, University Medical Center, Rotterdam on February 18th 2015. Secondary approval has been obtained from six of seven local ethics committees in the participating centers, and has been requested in the last. Verbal informed consent will be obtained from (potential) donors prior to filling out the questionnaires.

Dissemination

Results will be published in a scientific journal, and presented on national and international (medical) conferences. Data will be used to create a standardized surgical informed consent procedure for the live donor nephrectomy.

DISCUSSION

Informed consent is mandatory for every (surgical) procedure, but is even more important when it comes to living kidney donors, undergoing surgery for the benefit of others. Donor education, leading up to informed consent, needs to be carried out according to certain standards. According to national guidelines, those complications with an incidence of >1% or those with severe consequences need to be disclosed to patients (or donors)[23]. But if we would adhere to that standard, only bleeding, ileus and wound infection would have to be mentioned, in addition to the small risk of mortality (Kortram et al, meta-analysis, unpublished). A recent survey study among Dutch kidney transplant surgeons demonstrates that even these complications are not always disclosed to donors (Kortram et al, survey, unpublished). Moreover, it is questionable whether this information is sufficient for potential kidney donors. They are not patients, and they do not benefit from undergoing this procedure. Every
complication is one too many, and donors need to be aware of the risks and details of the donation procedure. It is thus argued that donors may need more and/or different information than the three most frequently encountered complications to be optimally prepared for donor nephrectomy and the postoperative course. However, it has also been proposed that donors do not use the same decision-making strategy patients use. Instead of carefully weighing all risks and benefits, they make their decision upon the first moment of hearing of the possibility, and never change their mind, regardless of the information they receive during the educational and informed consent process[20, 21]. So how does the provided information relate to donor comprehension? And how does donor comprehension relate to donor satisfaction? After all, even if donor comprehension is lacking, but satisfaction rates are high, is it even necessary to change our current policy? There have been a number of studies assessing donors’ knowledge of kidney donation and transplantation[14, 18], but none of these tests were as specific as the pop quiz used in the PRINCE project. In addition, donors were only tested at one moment during the educational process. During the PRINCE project, comprehension will be measured before and after information provision in all Dutch transplant centers. The ideal design for the present study would be a longitudinal cohort study. To administer the first pop quiz at the moment a potential donor first comes to the outpatient nephrology clinic, then follow them through their educational course to the surgical outpatient clinic, the ward and postoperatively. However, in many cases, the time interval from the first donor contact to actual donor nephrectomy exceeds a year, if donor nephrectomy takes place at all. Of the 422 potential donors evaluated at our center in 2013, 227 were either rejected or decided not to proceed with the donation process themselves. In February 2015, 136 of the remaining 195 donors had already undergone surgery, and 59 were still being evaluated, on the waiting list, or postponed because their recipient’s own kidney function was still good enough. Even though these numbers are from one center only, they do indicate that a longitudinal cohort, with the preferred sample size would take at least two years to complete follow-up. Comparing two different
cohorts; a baseline group at the outpatient nephrology clinic and a control group on the surgical ward on the day of admission may provide us with the same information, especially since it will be a nationwide study with a large number of patients. Using a thorough baseline questionnaire for both groups will enable us to check whether the groups are indeed similar. By introducing a random sample longitudinal cohort, with audio recordings of the surgical consultations, results of the two other cohorts can be compared to this group to verify reliability of the results. Using this approach for the PRINCE project will give us a clear overview of the actual gained knowledge during the educational process. In addition, donor satisfaction will be evaluated and related to donor comprehension. By assessing what information donors need, and want to hear to prepare them for surgery and convalescence, the basis for a standardized informed consent procedure for live donor nephrectomy can be created. It has to be taken into account that even in a small country as The Netherlands with generally harmonized protocols, details in local practice vary with regards to hospital logistics, but also with regards to the different techniques for live donor nephrectomy employed by each center. The standardized format will have to allow for (small) modifications to fit the situation in each individual kidney transplant center.

LIST OF ABBREVIATIONS
PRINCE – Process of Informed Consent Evaluation

SD – Standard Deviation

SPSS – Statistical Package for the Social Sciences

AUTHORS’ CONTRIBUTIONS

KK designed and wrote the study protocol and this manuscript

FJMFD supervised design and writing of the study protocol and this manuscript

SYI designed the scoring system for the pop quiz and corrected this manuscript

CWNL wrote the statistical part of the protocol and this manuscript

JNMIJ, FHCDa, MHLC, LWEH, HSH, AWJH, JJH, MMI, SAN, JR, RJT and JW participated in designing the study protocol and corrected this manuscript

EQWS participated in the introduction of the study in the participating centers and data-collection

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COMPETING INTEREST
The authors declare no conflicts of interest.

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ABSTRACT

Introduction Informed consent is mandatory for every (surgical) procedure, but is even more important when it comes to living kidney donors, undergoing surgery for the benefit of others. Donor education, leading to informed consent, needs to be carried out according to certain standards. Informed consent procedures for live donor nephrectomy vary per center, even per individual healthcare professional. By assessing what information donors need to hear to prepare them for the operation and convalescence, the basis for a standardized, uniform surgical informed consent procedure for live donor nephrectomy can be created.

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Ethics and dissemination Approval for this study was obtained from the medical ethical committee of the Erasmus MC, University Medical Center, Rotterdam, February 18th 2015. Secondary approval has been obtained from the local ethics committees in six participating centers. Approval in the last center has been requested. Results will be published in a scientific journal.
Registration NTR5374

Strengths and limitations of this study

Strengths:

- Unique in topic and design
- National study
- Large cohorts

Limitations:

- Use of unvalidated questionnaires
The Netherlands have a high rate of live kidney donation (31 living donors per million of population[1]), with more than half of all kidney transplants involving a living donor. In 2014, 534 live donor nephrectomies were performed out of a total of 1004 kidney transplantations (53.2%)[2]. One of the most successful paired kidney exchange (PKE) programs have been created in the Netherlands[3, 4], and many trials assessing the surgical procedure for the live donor nephrectomy have been initiated here[5-8]. With very low complication and mortality rates, live donor nephrectomy is a safe, low-risk elective surgical procedure. In contrast to patients, living donors are (generally) healthy individuals, from whom an organ is removed foremost for the benefit of others, although donors may gain psychological benefit. It is of the utmost importance that any patient is correctly informed about the specific details, risks and alternatives of a procedure, but the unique character of the live donor nephrectomy may warrant an extra vigilant approach to the informed consent process. Informed consent practices and procedures vary per center, and even per individual health care professional[9]. Standardization of this procedure, with regard to format, and contents, will greatly aid the transplant community, and improve the quality of care for living kidney donors[10, 11].

The need for a standardized format, ensuring disclosure of all important details and risks, further increases since extended criteria donors (e.g. overweight/obese donors, older donors, donors with hypertension and/or vascular multiplicity/anomalies) are increasingly being accepted[12]. These individuals could be more prone to complications, and potential donors must be well aware of the risks involved with their upcoming procedure, as well as future perspectives with only one kidney. These donors go through numerous steps during the informed consent procedure. In most Dutch centers, they are first seen by a nephrologist, transplant coordinator or nurse practitioner, who provide a lot of information about the donation procedure. In addition, most are evaluated by a social worker and some by a psychologist. The last person in the chain of information provision is usually the surgeon, who is responsible for performing the donor
nephrectomy. In addition, the relevance of uniform information provision is underlined by paired
echange procedures, which are more frequently employed these days. It is not uncommon in
the Netherlands that donors receive their education/information in one center but surgery in
another. They may receive different information in these centers, which may be confusing. The
Dutch situation is herein quite unique and stands in contrast to PKE programs in some other
countries where the donor and recipient both remain in their own centers but the donor organ is
transported[3, 4]. It is therefore mandatory that the Dutch transplant centers adopt a
standardized, uniform informed consent procedure. But even if donors do not travel between
centers, as is the case in many other countries, medical professionals as well as donors will still
benefit greatly from a standardized format.

The question remains what this standardized format should comprise. The living donor
nephrectomy itself has become fully implemented in the general practice and much more
information has become available regarding outcome and possible peri- and postoperative
complications (Kortram et al., submitted). Due to these developments living kidney donation has
gained ground over the past decades, and numbers are increasing worldwide. This merits a
revisited opinion on information disclosure and consent. Although the informed consent process
has evolved alongside the surgical procedure in an attempt to incorporate the most up to date
knowledge and transfer it to potential donors in an understandable fashion, it has yet to be
brought to perfection[9].

Every physician, ethicist or legalist will agree that a person giving consent should be “fully
informed”, “free of coercion” and “competent”[13], but there is no consensus on details to be
provided during the process, nor the manner in which these should be delivered. There are
many different policies and guidelines outlining matters that should be disclosed to potential
donors, but details are often not specified[14, 15]. These differences make it impossible for
healthcare professionals to practice a uniform strategy and it is challenging to determine which
patient has received which information. Recent data demonstrate that when tested on their knowledge, a large number of living kidney donors underestimate the complications and risks of living donor nephrectomy[16]. Surman et al. published similar findings in renal and liver transplant patients, revealing significant conceptual limitations to their knowledge about their postoperative situation, underlining the importance of adequate preoperative education[17]. Recently, a study performed by Gordon et al. was published regarding informed consent in living liver donors, again demonstrating that a large number of donors report a lack of understanding of the provided information (40%)[18]. Comparable results are demonstrated in other studies, where donors report varying degrees of (dis)satisfaction with and misunderstanding of provided information[10, 19, 20]. The question is raised whether the necessary information has not been provided correctly, whether donors simply not understand or remember it, or, as has been proposed by some, whether they selectively filter information and thus miss particular risks associated with donation[21-23]. Standardizing the informed consent procedure will help us better understand and address this. Two studies have been performed preceding the initiation of the PRINCE project of which the protocol is described in this article. One pilot project, to assess feasibility and design details, and a survey among Dutch kidney transplant surgeons to assess the current situation regarding live donor nephrectomy and informed consent practices in the Netherlands. These studies will be briefly highlighted in the following paragraph.

**Pilot study**

A pilot study was performed (Kortram et al, submitted), preoperative surgical outpatient clinic visits of 46 potential living kidney donors were observed and provided information was scored. Immediately after giving consent for donor nephrectomy, and again on the day of admission for the operation, donors received a questionnaire testing their knowledge of the upcoming operation. They received an evaluation questionnaire regarding their satisfaction with and
understanding of the informed consent procedure 6-12 weeks postoperatively. After completion of the pilot study, pop quiz questions were rephrased where necessary, and the scoring system was adjusted.

Survey

A web-based survey was created to assess the current situation in the eight Dutch transplant centers (Kortram et al, submitted). All surgeons who were possibly involved, or had been so in the past, in live kidney donation were invited to complete the survey (n=50). The response rate was 98% (N=49, of which 32 were still active in living donor education). Respondents were asked which complications they discussed with potential donors during the informed consent process for live donor nephrectomy. Important complications were not always disclosed: bleeding was the only complication every surgeon mentioned. Risk of death was always mentioned by 16 surgeons (50%), sometimes by 12 (37.5%), and four surgeons (12.5%) never disclosed this disastrous complication. Thus, some improvements can be made regarding information provision.

METHODS AND ANALYSIS

Design

The PRINCE (Process of Informed Consent Evaluation) Inventory project is designed as a prospective, multicenter cohort study. The study is conducted in the eight Dutch kidney transplant centers, which are all University Medical Centers (to which transplantation is confined).

The study is divided into two parts: a cross-sectional study (Cohorts 1 & 3) and a longitudinal study (Cohort 2). Both parts are prospective studies. Figure 1 presents a schematic overview of the different cohorts.
The cross-sectional study comprises pop-quizzing two cohorts of donors at different stages during the pre-donation period. The cross-sectional design is chosen to include as many donors as possible. Cohort 1 will be included when the potential donors first present themselves to the hospital, at the outpatient nephrology clinic, prior to having spoken to any member of the transplant team. The second group will be included one day preoperatively on admission for donor nephrectomy (Cohort 3). These donors will have received all information possible from different members of the transplant team.

Both groups of donors will be asked to fill out a pop quiz regarding their knowledge of the donor nephrectomy procedure, the possible short- and long-term complications and details about hospital admission and convalescence. The second group of donors will receive an additional questionnaire three months after surgery to assess their satisfaction with the educational- and informed consent procedure retrospectively.

The donors included in the longitudinal part of the study, i.e. Cohort 2, will be followed more closely to obtain a detailed conception of the informed consent process in the eight different centers. The donors that are eligible for inclusion in Cohort 2 are those donors already included in Cohort 1, that are being referred to the surgical outpatient clinic. This will mainly be influenced by their recipient’s status (preemptive, comorbidity etc.), and whether the donor has been approved by the nephrologist. The surgical consult will be recorded (audio only). These recordings will be analyzed using a standardized checklist, to assess which complications and other details are specifically disclosed by the surgeon. Donors in this cohort will be asked to fill out the same pop quiz as the first cohort, immediately after the surgical consult and again on the day of admission. They will also receive the evaluation questionnaire three months after surgery.
Objectives

The primary objectives of this inventory project are to assess the current status of the informed consent procedure for the live donor nephrectomy in all Dutch kidney transplant centers with regard to the procedure, donor knowledge and satisfaction. The ultimate objective is to eventually create a standardized format informed consent procedure.

Study population

The study population is divided into three cohorts. Cohort 1 comprises all potential living kidney donors that are seen at the outpatient nephrology clinic. Exclusion criteria for this cohort are: inability to understand the Dutch language, prior donation education in a kidney transplant center, age < 18 years and a mental illness prohibiting informed consent. Cohort 2 is obtained from a sample of referred Cohort 1 donors. The first 10 donors in each center that are referred to the surgical outpatient clinic will be included. Cohort 3 comprises all donors that are admitted to the surgical ward for live donor nephrectomy. This includes those donors that have already been included in cohort 2. Exclusion criteria for the latter two cohorts are: inability to understand the Dutch language, age < 18 years, and a mental illness prohibiting informed consent.

Sample size calculation

Since this study is an inventory project, making a comparison of informative findings rather than performing one specific measurement, a sample size calculation is not applicable. The total number of live donor nephrectomies differs between the eight centers (figure 2), and it is therefore unrealistic to set the same goal for every center. But it is necessary that all participating centers provide a large enough number of subjects, seen by preferably all, but at least a number of different members of the transplant team to eliminate, as much as possible, inter-observer and timing-related variations in donor education. The following inclusion aims are set: 400 donors for cohort 1 (50 donors in each center), 80 for cohort 2 (10 donors in each
center) and 200 for cohort 3 (Number of donors per center calculated based on procedures performed in 2014).

<< Figure 2 >>

**Primary & Secondary endpoints**

The first main study parameter is donor knowledge of the donation procedure. This will be assessed by means of a pop quiz score. Scores will be compared between the different cohorts and/or time-intervals. The elements to be included in the standardized informed consent format comprise the second main study parameter. These items will be assessed by different means. Obviously, some items will have to be included, based on the knowledge we already have from experience and the currently available literature (Kortram et al., submitted). The audio recordings of the Cohort 2 donors will provide us with information about the currently disclosed items in each center. We will try to correlate this to donor knowledge of the individual items on our checklist. In addition; all Cohort 3 donors receive an evaluation questionnaire in which they are asked whether they’ve missed anything during the informational process.

The first secondary study parameter is the manner of obtaining informed consent and the contents hereof in the eight Dutch transplant centers. This parameter is a descriptive parameter, which cannot be directly measured. This parameter will be assessed by interviews with the (para)medical staff in each transplant center, and by observation on site. Some aspects of the process itself will be collected and compared between centers: e.g. how many visits (on average) each donor has, the location where donors are seen (outpatient clinic, ward), the manner of obtaining consent (assumed, verbal, written), and who is responsible for obtaining consent (surgeon, nephrologist). These procedures will be compared to create the optimal format for all Dutch centers. In addition, provided information material (e.g. only orally...
distributed, leaflets, DVDs, websites, information evenings) will be assessed and compared between centers.

Donor satisfaction will be measured using the visual analogue scale (VAS-score, 0-10) in addition to describing questions. The last secondary parameter that will be assessed is the correlation between the donor’s knowledge and the surgeon’s estimate thereof. Surgeons will be asked to “predict” their donor’s score after the consultation, using a 0-10 scale, 0 meaning no knowledge whatsoever and 10 meaning perfect reproduction of all details. This will be correlated to the donor’s pop quiz scores.

Data collection & follow-up

Each donor will receive an anonymous study number, which will be used for the database. All subjects will be asked to fill out one or more, with a maximum of three pop quizzes. Donors included in cohort 3 will also be sent an evaluation questionnaire three months postoperatively. In addition, every donor is asked to fill out a baseline questionnaire with general questions regarding social economic status, religion and donation activities. The random sample of donors that will be followed longitudinally will be monitored more closely. The preoperative surgical consult at the outpatient clinic will be recorded (audio only), and these consults will be scored using a standardized checklist. These donors will receive one additional pop quiz immediately after the surgical consult. All other tests and procedures will be according to local protocol for the screening and treatment of living kidney donors.

Statistical Analyses

Statistical analysis will be performed using SPSS version 21 and R version 3.1.2. Dichotomous data and counts will be presented in frequencies. Continuous data will be presented in means with a standard deviation (SD) or median value with a range. In addition, some information will be presented in a literal descriptive fashion (i.e. specific answers to the pop-quiz questions).
Differences between scores will be compared by the independent sample t-test, the pairwise comparison t-test or One-Way ANOVA. To compare differences in mentioning frequencies of individual complications between Cohort 1 and Cohort 3, Chi\(^2\) tests will be performed. For the donors in Cohort 2 the McNemar test will be performed to compare individual mentioning frequencies at the different time intervals. The McNemar test compares the number of those who first scored positive and then negative with the number who first scored negative and then positive: if these numbers differ significantly from each other an increase or decrease can be concluded. A p-value of <0.05 will be considered statistically significant. Multivariate analysis will be performed using linear regression. If necessary, bootstrapping will be applied. Stratification will be applied for center.

Feasibility

Approval from the medical ethical committee for the PRINCE project was obtained on February 8\(^{th}\) 2015, and the first donor was included on March 30\(^{th}\) 2015. At this moment approval of local ethical committees has been obtained in six of seven of the other participating centers, and donors are being included in the different cohorts in these centers. In the last center, approval from the local ethics committee has been requested.

ETHICS AND DISSEMINATION

Ethics

Approval for this study was obtained from the medical ethical committee of the Erasmus MC, University Medical Center, Rotterdam, The Netherlands, on February 18\(^{th}\) 2015. Secondary approval has been obtained from six of seven local ethics committees in the participating centers, and has been requested in the last. Verbal informed consent will be obtained from (potential) donors prior to filling out the questionnaires.
Dissemination

Results will be published in a scientific journal, and presented on national and international (medical) conferences. Data will be used to create a standardized surgical informed consent procedure for the live donor nephrectomy.

DISCUSSION

Informed consent is mandatory for every (surgical) procedure, but is even more important when it comes to living kidney donors, undergoing surgery for the benefit of others. Donor education, leading up to informed consent, needs to be carried out according to certain standards. According to national guidelines, those complications with an incidence of >1% or those with severe consequences need to be disclosed to patients (or donors)[24]. But if we would adhere to that standard, only bleeding, ileus and wound infection would have to be mentioned, in addition to the small risk of mortality (Kortram et al, meta-analysis, unpublished).

A recent survey study among Dutch kidney transplant surgeons demonstrates that even these complications are not always disclosed to donors (Kortram et al, survey, unpublished). Moreover, it is questionable whether this information is sufficient for potential kidney donors. They are not patients, and they do not directly benefit from undergoing this procedure. Every complication is one too many, and donors need to be aware of the risks and details of the donation procedure. It is thus argued that donors may need more and/or different information than the three most frequently encountered complications to be optimally prepared for donor nephrectomy and the postoperative course.

However, it has also been proposed that donors do not use the same decision-making strategy that patients use. Instead of carefully weighing all risks and benefits, many make their decision upon the first moment of hearing of the possibility, and many never change their mind,
regardless of the information they receive during the educational and informed consent process[21, 22], although more recent studies do bring in some nuance[25].

So how does the provided information relate to donor knowledge? And how does donor knowledge relate to donor satisfaction? After all, even if donor knowledge is lacking, but satisfaction rates are high, is it even necessary to change our current policy? There have been a number of studies assessing donors’ knowledge of kidney donation and transplantation[16, 19], but none of these tests were as specific as the pop quiz to be used in the PRINCE project.

In addition, donors were only tested at one moment during the educational process. During the PRINCE project, donor knowledge will be measured before and after information provision in all Dutch transplant centers. The ideal design for the present study would be a longitudinal cohort study. To administer the first pop quiz at the moment a potential donor first comes to the outpatient nephrology clinic, then follow them through their educational course to the surgical outpatient clinic, the ward and postoperatively. However, in many cases, the time interval from the first donor contact to actual donor nephrectomy exceeds a year, if donor nephrectomy takes place at all. Of the 422 potential donors evaluated at our center in 2013, 227 were either rejected or decided not to proceed with the donation process themselves. In February 2015, 136 of the remaining 195 donors had already undergone surgery, and 59 were still being evaluated, on the waiting list, or postponed because their recipient’s own kidney function was still good enough. Even though these numbers are from one center only, they do indicate that a longitudinal cohort, with the preferred sample size would take at least two years to complete follow-up. Comparing two different cohorts; a baseline group at the outpatient nephrology clinic and a control group on the surgical ward on the day of admission may provide us with the same information, especially since it will be a nationwide study with a large number of patients. Using a thorough baseline questionnaire for both groups will enable us to check whether the groups are indeed similar. By introducing an additional sample in the longitudinal cohort, with audio
recordings of the surgical consultations, results of the two other cohorts can be compared to this
group to verify reliability of the results.

Even though we believe that the current format for the PRINCE project is the best possible
design to assess the informed consent procedure for the live donor nephrectomy, a number of
limitations are foreseen.

First of all, there are no validated questionnaires to assess donor knowledge to the extent
pursued in our study. Validation of a knowledge test with open questions instead of multiple-
choice is virtually impossible, since donors may learn or forget specific information at different
time points. Using multiple-choice questions is much easier to compare scores, but we believe
an open question, requiring an answer in the donor’s own words provides more reliable
information. This way, we can be sure that they actually know this information, and not just
check the boxes of words that they vaguely recall having been told about.

The open questions do again pose as a possible limitation. Donors may misinterpret the
question, as we have already seen during the PILOT project, in which some answered the
question about the surgical technique with "good" or "very careful". In addition, they may list one
or two complications, and not everything they possibly know.

Last, a good pop-quiz score does not necessarily equal adequate donor comprehension.
Donors may write down “hand-assisted laparoscopic donor nephrectomy” as the surgical
technique, because they remember the surgeon talking about this, score 2 points, but have no
idea what this actually means. On the other hand, a donor may write down “key hole surgery”,
score and score only one point, have a far better understanding of what is going to happen
during the procedure.

Using the chosen approach for the PRINCE project will give us a clear overview of the actual
gained knowledge during the educational process. In addition, donor satisfaction will be
evaluated and related to donor knowledge. By assessing what information donors need, and
want to hear to prepare them for surgery and convalescence, the basis for a standardized informed consent procedure for live donor nephrectomy can be created. It has to be taken into account that even in a small country as The Netherlands with generally harmonized protocols, details in local practice vary with regards to hospital logistics, but also with regards to the different techniques for live donor nephrectomy employed by each center. The standardized format will have to allow for (small) modifications to fit the situation in each individual kidney transplant center.
LIST OF ABBREVIATIONS

PRINCE – Process of Informed Consent Evaluation

SD – Standard Deviation

SPSS – Statistical Package for the Social Sciences

AUTHORS’ CONTRIBUTIONS

KK designed and wrote the study protocol and this manuscript

FJMFD supervised design and writing of the study protocol and this manuscript

SYI designed the scoring system for the pop quiz and corrected this manuscript

CWNL wrote the statistical part of the protocol and this manuscript

JNMIJ, FHCdA, MHLC, LWEH, HSH, AWJH, JJH, MMI, SAN, JR, RJT and JW participated in designing the study protocol and corrected this manuscript

EQWS participated in the introduction of the study in the participating centers and data-collection

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COMPETING INTEREST

The authors declare no conflicts of interest.

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REFERENCES


Figure 1. Schematic overview of the three cohorts.
114x75mm (300 x 300 DPI)
Figure 2. Number of live donor nephrectomies per center in 2014
97x49mm (300 x 300 DPI)
1. How well, on a scale of 1 – 10, do you feel to be prepared for the surgery and the convalescence period? Please draw a vertical line on the rectangle below, in which 0 is absolutely not prepared and 10 = couldn’t have been any better prepared.

![Rectangle with line indicating preparedness scale]

2. What type of surgery will you undergo? Think about surgical technique, the number of scars you will get, and where these scars will be.

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

How did you learn this information? (Please choose all answers that apply)

☐ Explained by Surgeon/Urologist
☐ Explained by Nephrologist
☐ Explained by nurse/transplant coordinator
☐ Heard about it during information evening
☐ Explained by family/friends
☐ Read in information provided by the hospital
☐ Read in information looked up myself

3. Which short-term problems and complications can occur? Please write down all answers you can think of

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

How did you learn this information? (Please choose all answers that apply)

☐ Explained by Surgeon/Urologist
☐ Explained by Nephrologist
4. Which long-term problems and complications can occur?
Please write down all answers you can think of

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

How did you learn this information? (Please choose all answers that apply)

□ Explained by Surgeon/Urologist
□ Explained by Nephrologist
□ Explained by nurse/transplant coordinator
□ Heard about it during information evening
□ Explained by family/friends
□ Read in information provided by the hospital
□ Read in information looked up myself

5. How many days do you expect to be admitted in the hospital?
Please write down the total number of days, before and after the surgery

_____________________________________________________________________________

How did you learn this information? (Please choose all answers that apply)

□ Explained by Surgeon/Urologist
□ Explained by Nephrologist
□ Explained by nurse/transplant coordinator
□ Heard about it during information evening
□ Explained by family/friends
□ Read in information provided by the hospital
□ Read in information looked up myself
6. How long do you expect it will be before you can perform your work / your normal daily activities?  
Please strikethrough as appropriate

______________________________ Weeks/ Months

How did you learn this information? (Please choose all answers that apply)

☐ Explained by Surgeon/Urologist
☐ Explained by Nephrologist
☐ Explained by nurse/transplant coordinator
☐ Heard about it during information evening
☐ Explained by family/friends
☐ Read in information provided by the hospital
☐ Read in information looked up myself

STUDY NUMBER: __________