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Published in:
BMJ Open

DOI:
10.1136/bmjopen-2015-010594

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2016

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

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Towards a standardised informed consent procedure for live donor nephrectomy: the PRINCE (Process of Informed Consent Evaluation) project – study protocol for a nationwide prospective cohort study

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ABSTRACT

Introduction: Informed consent is mandatory for all (surgical) procedures, but it 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 centre, and even per individual healthcare professional. The basis for a standardised, uniform surgical informed consent procedure for live donor nephrectomy can be created by assessing what information donors need to hear to prepare them for the operation and convalescence.

Methods and analysis: The PRINCE (Process of Informed Consent Evaluation) project is a prospective, multicentre cohort study, to be carried out in all eight Dutch kidney transplant centres. Donor knowledge of the 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 centres) will be compared with a control group, the members of which receive the pop quiz on the day of admission for donor nephrectomy. Donor satisfaction will be evaluated for all donors who completed the admission pop-quiz. The primary end point is donor knowledge. In addition, those elements that have to be included in the standardised format informed consent procedure for live donor nephrectomy can be created by assessing what information donors need to hear to prepare them for the operation and convalescence.

Strengths and limitations of this study

▪ The PRINCE study is unique in topic and design.
▪ The PRINCE study is a national study, carried out in all transplant centers.
▪ The three cohorts in the PRINCE study are large.
▪ The use of unvalidated questionnaires is a limitation of the PRINCE study.

INTRODUCTION

The Netherlands has a high rate of live kidney donation (31 living donors per million population1), 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) programmes has been created in the Netherlands,3,4 and many trials assessing the surgical procedure for 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


Prepublication history and additional material is available. To view please visit the journal (http://dx.doi.org/10.1136/bmjopen-2015-010594).

All authors are members of the National working group on Informed Consent Live Kidney Donation.

Received 18 November 2015
Revised 11 January 2016
Accepted 21 January 2016

CrossMark

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Erasmus MC, University Medical Center, Rotterdam, on 18 February 2015. Secondary approval has been obtained from the local ethics committees in six participating centres. Approval in the last centre has been sought. Results: Outcome will be published in a scientific journal.

Trial registration number: NTR5374; Pre-results.
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 live donor nephrectomy may warrant an extra vigilant approach to the informed consent process. Informed consent practices and procedures vary per centre, and even per individual healthcare professional. Standardisation 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.

The need for a standardised format ensuring disclosure of all important details and risks further increases since extended criteria donors (eg, overweight/obese donors, older donors, donors with hypertension and/or vascular multiplicity/anomalies) are increasingly being accepted. These individuals could be more prone to complications, and potential donors must be well aware of the risks involved in their upcoming procedure, as well as future prospects with only one kidney. These donors go through numerous steps during the informed consent procedure. In most Dutch centres, they are first seen by a nephrologist, transplant coordinator or nurse practitioner, who provides 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 exchange procedures, which are more frequently employed these days. In the Netherlands, it is not uncommon for donors to receive their education/information in one centre and surgery in another. They may receive differing pieces of information in these centres, which may be confusing. The Dutch situation is in this regard quite unique and stands in contrast to PKE programmes in some other countries, where the donor and recipient each remain in their respective centre with the donor organ being transported. It is therefore mandatory that the Dutch transplant centres adopt a standardised, uniform informed consent procedure. But even if donors do not travel between centres, as is the case in many other countries, medical professionals as well as donors will still benefit greatly from a standardised format.

The question remains as to what this standardised 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 perioperative and postoperative complications (K Kortram, J Ijzermans, F Dor. Peri-operative Events and Complications in Minimally-Invasive Live Donor Nephrectomy. A Systematic Review and Meta-Analysis. Accepted, 2016). Owing 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.

Every physician, ethicist or legalist will agree that a person giving consent should be ‘fully informed’, ‘free of coercion’ and ‘competent’, 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. These differences make it impossible for healthcare professionals to practise 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. Surman published similar findings in patients with renal and liver transplant, revealing significant conceptual limitations to their knowledge about their post-operative situation, underlining the importance of adequate preoperative education. 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%). Comparable results are demonstrated in other studies, where donors report varying degrees of (dis)satisfaction with and misunderstanding of provided information.

The question is raised of whether or not the necessary information has been provided correctly, whether donors simply do 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. Standardising the informed consent procedure will help us better understand and address this. Two studies have been performed preceding the initiation of the PRINCE (Process of Informed Consent Evaluation) project, of which the protocol is described in this article. One is a pilot project to assess feasibility and design details, and the other, 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 paragraphs.

Pilot study
A pilot study was performed (K Kortram, E Spoon, C Looman, et al. Donor Knowledge of Provided Information During Informed Consent Process in Live Donor Nephrectomy. A Pilot study, Submitted, 2016) in
which preoperative surgical outpatient clinic visits of 46 potential living kidney donors were observed and the information provided 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 centres (K Kortram, J Ijzermans, F Dor. Towards a standardized informed consent procedure for live donor nephrectomy: What do surgeons tell potential donors? Submitted, 2016). All surgeons who were possibly involved, or had been 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 4 surgeons (12.5%) never disclosed this disastrous complication. Thus, some improvements can be made regarding information provision.

METHODS AND ANALYSIS
Design
The PRINCE Inventory project is designed as a prospective, multicentre cohort study. The study is conducted in the eight Dutch kidney transplant centres, which are all university medical centres (to which transplantation is confined).

The study is divided into two parts: a cross-sectional study (cohorts 1 and 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 predonation 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 1 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-term and long-term complications, and details about hospital admission and convalescence (see online supplementary material appendix 1). The second group of donors will receive an additional questionnaire 3 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, that is, cohort 2, will be followed more closely to obtain a detailed conception of the informed consent process in the eight different centres. The donors who are eligible for inclusion in cohort 2 are those donors already included in cohort 1 who are being referred to the surgical outpatient clinic. This will mainly be influenced by their recipient’s status (pre-emptive, comorbidity, etc), and whether the donor has been approved by the nephrologist. The surgical consult will be recorded (audio only). These recordings will be analysed using a standardised 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 3 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 centres with regard to the procedure, donor knowledge and satisfaction. The ultimate objective is to eventually create a standardised format informed consent procedure.

Study population
The study population is divided into three cohorts. Cohort 1 comprises all potential living kidney donors who 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 centre, 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 centre who are referred to the surgical outpatient clinic will be included. Cohort 3 comprises all donors who are admitted to the surgical ward for live donor nephrectomy. This includes those donors who 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 centres (figure 2), and it is therefore unrealistic to set the same goal for every centre. But it is necessary that all participating centres provide a large enough number of participants, seen by preferably all, but at least a number of different members of the transplant team, to eliminate, as much as possible, interobserver and timing-related variations in donor education. The following inclusion aims are set: 400 donors for cohort 1 (50 donors in each centre), 80 for cohort 2 (10 donors in each centre) and 200 for cohort 3 (number of donors per centre calculated based on procedures performed in 2014).

**Primary and secondary end points**

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 standardised informed consent format comprise the second main study parameter. These items will be assessed using different means. Obviously, some items will have to be included, based on the knowledge we already have from experience and the currently available literature (K Kortram, J Ijzermans, F Dor. Peri-operative Events and Complications in Minimally-Invasive Live Donor Nephrectomy. A Systematic Review and Meta-Analysis. Accepted, 2016). The audio recordings of the cohort 2 donors will provide us with information about the currently disclosed items in each centre. 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 have missed anything during the informational process.

The first secondary study parameter is the manner of obtaining informed consent and the contents thereof in the eight Dutch transplant centres. 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 centre, and by observation on site. Some aspects of the process itself will be collected and compared between centres: for example, 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 with create the optimal format for all Dutch centres. In addition, provided information material (eg, only orally distributed, leaflets, DVDs, websites, information evenings) will be assessed and compared between centres.

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 and follow-up**

Each donor will receive an anonymous study number, which will be used for the database. All participants 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 3 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 standardised 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 V.21 and R V.3.1.2. Dichotomous data and counts will be presented in frequencies. Continuous data will be presented in means with a SD or median value with a range. In addition, some information will be presented in a literal descriptive fashion (ie, specific answers to the pop quiz questions).

Differences between scores will be compared by the independent sample Student t test, the pairwise comparison Student t test or one-way analysis of variance (ANOVA). To compare differences in mentioning frequencies of individual complications between cohort 1 and 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 centre.

**Feasibility**

The subject of the PRINCE project is a much debated subject, and holds great interest among transplant professionals. The protocol for this study has been designed in a multidisciplinary working group, with delegates from each participating center. All participants are dedicated to the project and will do their utmost to complete the project successfully. The set numbers of donors to be included per center have been calculated based on the total live donor nephrectomies performed in 2014 at each center. Live donor nephrectomy rates are not expected to decline, and it thus seems reasonable that each center will reach its target within the indicated timeframe.

**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 18 February 2015. Secondary approval has been obtained from all of the other seven participating centres. 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 at national and international (medical) conferences. Data will be used to create a standardised surgical informed consent procedure for live donor nephrectomy.

**DISCUSSION**

Informed consent is mandatory for all (surgical) procedures, but it 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). 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 (K Kortram, J Ijzermans, F Dor. Peri-operative Events and Complications in Minimally-Invasive Live Donor Nephrectomy. A Systematic Review and Meta-Analysis. Accepted, 2016).

A recent survey study among Dutch kidney transplant surgeons demonstrates that even these complications are not always disclosed to donors (K Kortram, J Ijzermans, F Dor. Towards a standardized informed consent procedure for live donor nephrectomy: What do surgeons tell potential donors? Submitted, 2016). 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 at 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, although recent studies do bring in some nuances. So how does the provided information relate to donor knowledge? And how does donor knowledge relate to donor satisfaction? After all, 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, 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 point during the educational process. During the PRINCE project, donor knowledge will be measured before and after information provision in all Dutch transplant centres. The ideal design for the present study would be a longitudinal cohort study. The first pop quiz will be administered the moment a potential donor first comes to the outpatient nephrology clinic, the donor will then be followed through the educational course to the surgical outpatient clinic and the ward, as well as 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 centre 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 centre only, they do indicate that a longitudinal cohort with the preferred sample size would take at least 2 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 with 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 instead of multiple-choice questions 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 are not simply ticking off the boxes of answers they vaguely recall having been told about.

The open questions do again present 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, and score 2 points, but have no idea what this actually means. On the other hand, a donor may write down ‘key hole surgery’, and score only 1 point, but actually 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 standardised informed consent procedure for live donor nephrectomy can be created. It has to be taken into account that, even in a small country such as the Netherlands, with generally harmonised protocols, details in local practice vary with regard to hospital logistics, as well as with regard to the different techniques for live donor nephrectomy employed by each centre. The standardised format will have to allow for (small) modifications to fit the situation in each individual kidney transplant centre.

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Acknowledgements  The authors would like to thank the local study coordinators in the participating centres for their help with data collection, as well as thank all the nephrologists, surgeons, urologists, specialised nurses and transplant coordinators, for their help with this project and their input in the protocol.

Contributors  KK designed and wrote the study protocol. FJMFD supervised the designing and writing of the study protocol. SYI designed the scoring system for the pop quiz and edited the manuscript. CWNL wrote the statistical part of the protocol. JNM, FChD, MHLC, LWEvH, HSH, AWJH, JHvdH, MMI, SAN, JR, RJT and JvdW participated in designing the study protocol and edited the manuscript. EQWS participated in the introduction of the study in the participating centres and data-collection.

Funding  This project was funded by the Stichting Kwaliteitsgelden Medisch Specialisten (SKMS, Quality Foundation Funds Medical Specialists) and the Nierstichting Nederland (Dutch Kidney Foundation).

Competing interests  None declared.

Ethics approval  Approval was granted by the Medical Ethical Committee of the Erasmus MC, University Medical Center.

Provenance and peer review  Not commissioned; externally peer reviewed.

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BMJ Open 2016 6:
doi: 10.1136/bmjopen-2015-010594

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