SUMMARY OF PUBLISHED LIVING KIDNEY DONOR GUIDELINES
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<td>44 Informed Consent: donor peri-op complications</td>
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<tr>
<td>53 Recipient graft survival</td>
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<td>X NS</td>
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**UNOS (2013)**: 12:1-19
**CARI (2010)**: NEPHROLOGY 2010; 15, Supplement
**SEN ONT (2010)**: S.E.N. Guidelines Spanish Society of Nephrology (S.E.N.) and Spanish Transplant Organisation (ONT) recommendations for living-donor kidney Transplantation Full version in English and Spanish at www.revistanefrologia.com
NHMRC (2007) ORGAN AND TISSUE DONATION BY LIVING DONORS GUIDELINES FOR ETHICAL PRACTICE FOR HEALTH PROFESSIONALS (National Health and Medical Research Council) Endorsed 15 March, 2007


SR – Systematic Review
EB- Evidence based
EO – Expert Opinion
EO/EB – Combination of Expert Opinion and Evidence Review
EO/LR – Combination of Expert Opinion and Literature Review
EO/PG – Combination of Expert Opinion and Previously published Guidelines
PG – Previously published Guidelines
NS – Not Specified
1. Pre-Donation GFR

**ERBP (2013)**
- We recommend that all potential living kidney donors have their GFR assessed. *(1C)*
- We recommend that in cases where more exact knowledge on GFR is needed or where is doubt regarding the accuracy of GFR from estimation methods, a direct measurement of GFR is undertaken by exogenous clearance methods. *(Ungraded Statement)*
- We recommend that all potential donors should have a predicted GFR that is projected to remain above a satisfactory level after donation within the life-time of the donor as indicated in below figure (adapted with permission from Manas, 2011). *(Ungraded Statement)*

![Graph showing predicted GFR]({{site.url}}/images/graph.png)

**BTS (2011)**
- GFR should be measured using measured using a reference GFR procedure e.g. 51Cr EDTA. A prospective donor should not be considered for donation if the corrected GFR is predicted to fall below a satisfactory level of kidney function within the lifetime of the donor. A predicted GFR of at least 37.5 ml/min/1.73m2 at the age of 80 is recommended as a minimum standard. There is a lack of evidence to guide acceptable levels of kidney function for donors over 60 years of age *(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)*
- A living kidney donor with normal renal function prior to donation is at no greater risk than an individual in the general population of developing end stage renal disease after unilateral nephrectomy. Measurement of eGFR in living donors has not been validated to predict the risk
of long-term kidney disease and should not be used in this context (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

Table X. Acceptable GFR by donor age prior to donation

<table>
<thead>
<tr>
<th>Donor age (years)</th>
<th>Acceptable corrected GFR prior to donation (ml/min/1.73m2)</th>
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<tbody>
<tr>
<td>Up to 46</td>
<td>80</td>
</tr>
<tr>
<td>50</td>
<td>77</td>
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<tr>
<td>60</td>
<td>68</td>
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<tr>
<td>70</td>
<td>59</td>
</tr>
<tr>
<td>80</td>
<td>50</td>
</tr>
</tbody>
</table>

CARI (2010)

(Suggestions are based primarily on Level III and IV evidence) • An accurate assessment of the glomerular filtration rate (GFR) should be undertaken in all potential donors. The benefit of obtaining a directly measured GFR (thought to be more accurate) over an estimated GFR, has not been proven in live donors (refer to CARI guidelines titled ‘Use of estimated glomerular filtration rate to assess level of kidney function’ and ‘Direct measurement of glomerular filtration rate’). • When the GFR is estimated it is recommended that this be on the basis of serum creatinine using, for example, the Cockcroft-Gault (CG) formula or the Modified Diet in Renal Disease (MDRD). Measurement of creatinine clearance calculated from a 24 h urine collection is also acceptable, if collected accurately. The estimated glomerular filtration rate (eGFR) should be confirmed on at least two separate occasions. • If there is doubt regarding the GFR from estimated methods, further techniques can be used to assess or clarify this. Acceptable methods include a direct evaluation of the GFR by methods such as Cr-EDTA (nuclear GFR), iohexol or inulin clearance. • It is preferable not to accept kidneys from donors with GFR < 80 mL/min per 1.73 m2. (Recommendation is based on Expert Opinion and Low Level Evidence. No recommendations possible based on Level 1 or II evidence.)

What do other guidelines say? [CARI guidelines list other guidelines]

British Transplant Society (2005)
The potential kidney donor must have sufficient kidney function prior to donation to have an effective GFR at the age of 80 years independent of the age at which he/she donated. Acceptable GFR by donor age have been derived based on the reference data reported by Grewal and Blake and therefore assumes a constant GFR up until age 40. The acceptable GFR prior to donation have been established so as to achieve a predicted GFR at 80 greater than 37.5 mL/min per 1.73 m2 which is equal to the population mean at 80 minus 2 standard deviations. The acceptable GFR by donor age are as listed in the table below: Donor age (years) Acceptable corrected GFR prior to donation (mL/min per 1.73 m2)

<table>
<thead>
<tr>
<th>Donor age (years)</th>
<th>Acceptable corrected GFR prior to donation (mL/min per 1.73 m2)</th>
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<tbody>
<tr>
<td>Up to Age 40</td>
<td>86</td>
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<tr>
<td>50</td>
<td>77</td>
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<tr>
<td>60</td>
<td>68</td>
</tr>
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<td>70</td>
<td>59</td>
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<tr>
<td>80</td>
<td>50</td>
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GFR should be measured using an isotopic marker in all potential donors as alternate methods based on serum creatinine are not sufficiently accurate in this context and measured creatinine clearance, using timed urine collections, is susceptible to considerable inaccuracy. When renal function is normal but there is a significant difference in function between the two kidneys, the kidney with lower function should be used for transplantation.

European Renal Association-European Dialysis and Transplant Association (2000)
It is recommended that donor renal function be assessed by 24 h urine for creatinine clearance or a direct evaluation of the GFR by Cr-EDTA or iohexol or inulin clearance. As an optional assessment radionuclide determination of GFR as a separate evaluation of the function of the two kidneys. Donors with a reduced GFR in comparison to the normal range for age should be excluded.

The Amsterdam Forum on The Care of the Live Kidney Donor (2005)
Adopted the following consensus guideline regarding acceptable renal function:
• A GFR < 80 mL/min or 2 standard deviations below normal (based on age, gender and body surface area corrected to 1.73 m²) generally precludes donation.
• Kidneys from live donors with GFR 2 80 mL/min are associated with a relative risk of graft loss of 2.28 compared with those with greater pre-nephrectomy GFR.
• However, successful transplantation was noted from some, usually elderly living donors, with GFR as low as 65–70 mL/min, indicating a need for individualization and careful follow up of donors with GFR of <80 mL/min per 1.73 m².

It is recommended that in the absence of higher quality evidence, it is reasonable to refer to existing guidelines regarding the assessment and eligibility of potential living kidney donors (e.g. Amsterdam Forum). However, it is recommended that these guidelines not be used as absolute criteria where risk is poorly quantified or uncertain.

Renal focused evaluation to determine the presence of underlying kidney disease in the potential donor should include measurement of GFR (method not specified). CKD Stage 3 or less (defined as 30–59 mL/min per 1.73 m²) will typically exclude a living donor candidate from donating based upon scientific data of medical risk.

The Organ Procurement and Transplantation Network (2008)
Medical evaluation of potential donors should include:
• measurement of GFR by 24 h urine collection or equivalent testing. Possible exclusion criteria that may make an individual unsuitable for living donation includes:
• creatinine clearance < 80 mL/min per 1.73 m², or projected GFR with removal of one kidney at 80 years old of <40 mL/min per 1.73 m².

**SEN ONT (2010)**
Taking into account that after donation the GFR recovers up to 70% of its pre-donation level and that from 40 years old the kidneys lose renal function at a rate of 0.9ml/min/1.73m² per year, the minimum acceptable GFR to donate would be the GFR that meant the donor would reach 80 years old with a GFR of at least 37.5ml/min/1.73m². Minimum values calculated in ml/min/1.73m²: donors up to 40 years old 86; 50 years old 77; 60 years old 68; 70 years old 59.
**EAU (2009)**
Authors included "Abnormal glomerular filtration rate (GFR) for age" in their list of contraindications for donating. *(Source of recommendation unclear.)*

**NHMRC (2007)**
Authors directed readers toward the larger body of guidelines available describing the Medical Assessment of potential donors.

**UNOS/ASTS (2007)**
Authors include on the “Contraindications to Living Donation” a projected GFR with removal of one kidney at 80 years old of <40 cc/min/1.73m². *(Recommendation is based on Expert Opinion.)*

**CCDT (2006)**
Authors site recommendation made by the European Renal Association- European Dialysis and Transplant Association, 2000.

**Amsterdam Forum (2005)**
The following consensus guideline was adopted regarding acceptable renal function: a GFR <80 ml/minute or 2 standard deviations below normal (based on age, gender, and BSA corrected to 1.73/m²) generally preclude donation. Kidneys from live donors with GFR <80 ml/min are associated with relative risk of graft loss of 2.28 compared to those with greater prenephrectomy GFR. However, successful transplantation was noted from some, usually elderly, living donors with GFR as low as 65–70 ml/min, indicating a need for individualization and careful follow-up of donors with GFR of <80 ml/min/1.73/m². *(Recommendation based on Evidence-Based, Expert Opinion.)*
BTS (2011)

Divided Renal Function

- Divided renal function can be measured by combining a 51Cr-EDTA GFR measurement with a 99mTc-DMSA scan of the kidneys. This information is advisable before nephrectomy if there is considerable disparity in the size of the kidneys or anatomical abnormality is noted, but is otherwise not indicated. When renal function is normal but there is a significant (>10%) difference in function between the two kidneys, the kidney with lower function should normally be used for transplantation.

- Initial evaluation of renal anatomy in potential donors should include a renal ultrasound. Kidneys which differ significantly in size should be submitted to a split function isotope scan, and the kidney with poorer function should be selected for nephrectomy irrespective of vascular anatomy.

- A difference in size of 2 cm or more between the kidneys indicates that a split function isotope scan should be considered (a difference in function of more than 10% between the kidneys may be considered significant). (C2 – Recommendation is based on low quality evidence. Strength of evidence has been indicated at a “we suggest” level.)
UNOS (2013)
Authors describe “uncontrollable hypertension or history of hypertension with evidence of end stage organ damage” as an exclusion criterion. (Source of recommendation unclear.)

EBPG (2013)
- We recommend considering potential donors with a blood pressure <140/90 mmHg on at least three occasions without antihypertensive medication, as normotensive. (1C)
- We suggest measuring ambulatory blood pressure in potential donors who have office hypertension (blood pressure ≥140/90 mmHg) or who are taking pharmacological treatment for hypertension. (2C)
- We suggest well-controlled primary hypertension, as assessed by ambulatory blood pressure <130/85 mmHg, under treatment with maximum two anti-hypertensive drugs (diuretics included) is not considered a contraindication to living kidney donation. (2C)
- We recommend discouraging hypertensive donors with evidence of target organ damage such as left ventricular hypertrophy, hypertensive retinopathy and micro-albuminuria. (1C)
- We suggest that these potential donors could be re-evaluated for disappearance of this target organ damage after appropriate treatment. (2D)

BTS (2011)
- Potential donors with blood pressure <140/90 mmHg should be considered as normotensive and therefore suitable for nephrectomy on the basis of blood pressure (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Potential donors with ‘high normal’ blood pressure (>130/85 mmHg) should be warned about the greater future risk of developing hypertension and associated cardiovascular events and the need for monitoring (which should be recommended irrespective of nephrectomy). Additional assessment (24 hour blood pressure monitoring) should be considered but is not required (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- The definition and treatment of hypertension in prospective donors should follow the British Hypertension Society guidelines (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Office blood pressure measurements are sufficient for the assessment of the majority of potential donors. Ambulatory blood pressure monitoring should be considered for potential donors who have hypertension (blood pressure greater than 140/90 mmHg or who are taking pharmacological treatment for hypertension) and if this is normal (see below) donor nephrectomy is not precluded (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Living kidney donors should be encouraged to minimise the risk of hypertension and its consequences by lifestyle measures including smoking cessation, frequent exercise and, where appropriate, weight loss (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Prospective donors should be warned about the potential risks of hypertension, particularly if in a high risk group. Blood pressure measurement should be part of annual donor monitoring (B1
– Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

- The presence of mild-moderate hypertension that is controlled with 1-2 antihypertensive agents is not a contraindication to kidney donation providing significant end organ damage has been excluded (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

- Evidence of hypertensive end organ damage, poorly controlled hypertension, or hypertension that requires more than two drugs to achieve adequate control are relative contraindications to donor nephrectomy (C2 – Recommendation is based on low quality evidence. Strength of evidence has been indicated at a “we suggest” level.)

- Donors who develop hypertension should be managed according to British Hypertension Society guidelines and are at similar risk of developing complications as other patients with hypertension (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

CARI (2010)

- Potential living kidney donors should have their blood pressure (BP) measured on at least three occasions with a level less that 140/90 mmHg on all three occasions.

- Of one or more office BP measurements are elevated, white-coat hypertension may be excluded by:
  - 12 home BP measurements with an average less than 135/85 mmHg or
  - 24h ambulatory BP measurement (ABPM) with an average less than 135/85 mmHg.

- An elevated BP on the above definitions is a relative contraindication to donation.

- Donors with:
  - Evidence of end-organ damage related to hypertension (e.g. retinopathy, left ventricular hypertrophy, proteinuria), or
  - Poorly controlled BP (e.g. requiring more than two medications or BP still elevated), or
  - Other cardiovascular risk factors (e.g. elevated cholesterol, overweight, smoker, family history of cardiovascular disease) should not be considered for donation.

(SENSONT 2010)

- Blood pressure must be <140/90mm Hg on separate visits; average measurements in ABPM must be <135/85mm Hg during the day and <120/75 mm Hg during sleep.

- Someone with mild or moderate high blood pressure who has no other cardiovascular risks and has good renal function can donate as long as certain conditions are fulfilled: a) they are over 50 years old; b) they are not Afro-American; c) no evidence of damage to the internal organs as a result of HBP (ECG electrocardiogram, ophthalmoscopy, microalbuminuria <30mg/day); d) blood pressure can be controlled by lifestyle changes and the use of no more than one anti-hypertension drug, and e) there is a reasonable guarantee that the donor will follow the check-up period and treatment indefinitely.

EAU (2009)

Authors include “uncontrolled hypertension” on their list of absolute contraindications. (Source of recommendation unclear.)
CCDT (2006)
Authors site recommendation made by the Amsterdam Forum, 2005.

Amsterdam Forum (2005)
The following consensus guidelines regarding hypertensive donors were adopted following discussion by Greg Obrador, M.K. Mani and Ian Dittmer:

- Patients with a BP >140/90 by ABPM are generally not acceptable as donors.
- BP should preferably be measured by ABPM, particularly among older donors (>50 years) and/or those with high office BP readings.
- Some patients with easily controlled hypertension who meet other defined criteria (e.g., >50 years of age, GFR >80 ml/min, and urinary albumin excretion <30 mg/ day) may represent a low-risk group for development of kidney disease after donation and may be acceptable as kidney donors.
- Donors with hypertension should be regularly followed by a physician. (Recommendation based on Evidence-Based, Expert Opinion.)
4. Renal calculi

UNOS (2013)
Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24 hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine and sodium excretion. (Source of recommendation unclear.)

BTS (2011)
- In the absence of a significant metabolic abnormality, potential donors with a limited history of previous small calcium stones, or a small renal calculus on imaging, may still be considered as potential kidney donors. Full counselling of donor and recipient is required along with access to appropriate long term donor follow-up. (C2 – Recommendation is based on low quality evidence. Strength of evidence has been indicated at a “we suggest” level.)
- Potential donors with metabolic abnormalities detected on screening should be discussed with a specialist in renal stone disease. (C2 – Recommendation is based on low quality evidence. Strength of evidence has been indicated at a “we suggest” level.)

EAU (2009)
Authors list “history of bilateral kidney stones” as an absolute contraindication to living kidney donation. (Source of recommendation unclear.)

Amsterdam Forum (2005)
An asymptomatic potential donor with history of a single stone may be suitable for kidney donation if:
- No hypercalcuria, hyperuricemia, or metabolic acidosis.
- No cystinuria or hyperoxaluria.
- No urinary tract infection.
- Multiple stones or nephrocalcinosis are not evident on computed tomography (CT) scan.

Younger patients have a longer exposure to risk of recurrence. The risk of recurrence after any single stone is difficult to predict in any individual. The younger the donor age (age 25–35), the longer the exposure to the possibility of a recurrence.

Asymptomatic potential donor with current single stone may be suitable if:
- The donor meets the criteria shown previously for single stone formers, and current stone is 1.5 cm in size or potentially removable during transplant.

Ex vivo ureteroscopy is a technically feasible means of rendering a stone-bearing kidney stone free, without compromising ureteral integrity or renal allograft function. It is not known whether stone formers who donate a kidney have worse outcomes with respect to renal function compared to stone formers with two kidneys. However, a recurrent stone may not affect the function of a remaining kidney if it is carefully monitored.

Stone formers who should not donate are those with: 1) nephrocalcinosis on X ray or bilateral stone disease; and 2) stone types that have high recurrence rates and are difficult to prevent, such as:
• Cystine stones that have a high rate of recurrence and a need for urologic procedures in the donor.
• Struvite stones or infection stones that are difficult to eradicate and thus not feasible to transplant them into an immunosuppressed patient.
• Stones associated with inherited or other systemic disorders, such as primary or enteric hyperoxaluria, distal renal tubular acidosis, and sarcoid, because of the probability of a high rate of recurrence and the risk of renal insufficiency.
• Stones in the setting of inflammatory bowel disease with an increased risk of stones particularly after bowel resection, also increased risk of renal insufficiency.
• Recurrence while on appropriate treatment (i.e., failed therapy). *(Recommendation based on Evidence-Based, Expert Opinion.)*
UNOS (2013)
Centers must establish a protocol and follow their protocol for screening for Polycystic Kidney Disease or other inherited renal disease as guided by family history. (Source of recommendation unclear.)

British Transplantation Society (2011)
Multiple renal cysts may indicate polycystic kidney disease, although 11% of individuals over the age of 50 will have one or more simple renal cysts. Family history is important, and in those with a family history of polycystic kidney disease under the age of 40 years, the presence of two or more cysts (unilateral or bilateral) indicates autosomal dominant polycystic disease (APKD). It should be noted that a negative scan in this age group is associated with a 4% false negative rate, and even the presence of a single cyst is of sufficient concern that advice should be sought regarding genetic testing. For those aged 40 to 59 years, the absence of at least two cysts in each kidney gives a 100% negative predictive value for APKD, whilst for those older up to four cysts are acceptable in each kidney. It is, however, important to be aware that polycystic disease can arise from spontaneous mutations, and that a family history may not always be evident. Kidneys with large simple cysts (>2 cm) are likely to be suitable for donation but should undergo review in a multidisciplinary meeting including a radiologist, and may require further cross-sectional imaging.
6. Impaired fasting glucose or impaired glucose tolerance.

UNOS (2013)
Authors describe “diabetes” as an exclusion criterion. *(Source of recommendation unclear.)*

EBPG (2013)
- We recommend diabetes mellitus is a contraindication to donation, other than in exceptional circumstances. *(1D)*
- We suggest impaired glucose tolerance is not an absolute contraindication to donation. *(2C)*

British Transplantation Society (2011)
- All potential living kidney donors must have a fasting plasma glucose level checked. A level between 5.6–6.9 mmol/l is indicative of an impaired fasting glucose state and an oral glucose tolerance test (OGTT) must be undertaken *(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)*
- Prospective donors with an increased risk of Type 2 diabetes because of family history, ethnicity or obesity should also undergo an OGTT *(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)*
- If OGTT reveals a persistent impaired fasting glucose and/or an impaired glucose tolerance, then the risks of developing diabetes after donation must be carefully considered *(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)*
- Consideration of patients with diabetes as potential kidney donors requires very careful evaluation of the risks and benefits. In the absence of evidence of target organ damage and having ensured that other cardiovascular risk factors such as obesity, hypertension or hyperlipidaemia are optimally managed, diabetics can be considered for kidney donation after a thorough assessment of the lifetime risk of cardiovascular and progressive renal disease in the presence of a single kidney *(Expert Opinion, Recommendation not graded)*

CARI (2010)
- All potential living kidney donors should have a fasting plasma glucose level performed on at least two occasions. If the levels are:
  - 37 mmol/L on both occasions then the potential donor is diabetic and this is an absolute contraindication for living kidney donation,
  - 6.1–6.9 mmol/L on at least one occasion then this patient should have a 2 h oral glucose tolerance test (OGTT),
  - <6.1 mmol/L then this is normal and not a contraindication to donation.
- Patients at high risk for the development of type 2 diabetes mellitus (i.e. family history, age > 45 years, Aboriginal or Torres Strait Islander (ATSI) or obesity) should be screened with a 2 h OGTT.
- If the 2 h glucose of an OGTT results are:
  - 311.1 mmol/L then the patient is diabetic and this is an absolute contra-indication to living kidney donation,
  - 7.8–11.0 mmol/L then this patient has impaired glucose tolerance and this is an absolute contraindication to living kidney donation,
– <7.8 mmol/L is normal and not a contraindication to donation.
• A past history of gestational diabetes is an absolute contraindication to living kidney donation.  
  (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

WHAT DO THE OTHER GUIDELINES SAY? [CARI lists other guidelines]

... individuals with a history of diabetes or fasting blood glucose >7 mmol/L on at least two occasions (or 2 h glucose with OGTT >11.1 mmol/L should not donate.

We recommend . . . to refer to existing guidelines regarding the assessment and eligibility of potential living kidney donors (e.g. Amsterdam Forum).

European Renal Association-European Dialysis and Transplant Association (2000)
... exclusion criteria: . . . Diabetes mellitus . . .

UK Guidelines for Living Donor Kidney Transplantation (2005)
Diabetes mellitus is an absolute contraindication to living donation. Prospective donors with an increased risk of type 2 diabetes mellitus because of family history, ethnicity or obesity should undergo a glucose tolerance test and only be considered further as donors if this is normal.

SEN ONT (2010)
• Previous history or diagnosis of diabetes (baseline glycaemia >126 on two occasions, or non-fasting glycaemia or two hours after the OGTT>200) is an absolute contraindication to donation.
• Previous history of gestational diabetes is an absolute contraindication to donation given the high rate of developing diabetes later in life.
• Abnormal baseline glycaemia and hydrocarbon intolerance (glycaemia between 140 and 199 after 2 hours) are a relative contraindication to donation and must be assessed individually, taking into account the response to a simple health plan (diet, exercise, statins).

“We would be inclined to rule out donation when abnormal baseline glycaemia is in the upper range (110-125), or there is family history of the disease, other risk factors or metabolic syndrome as these show a higher tendency to develop diabetes and kidney disorders later in life.”

EAU (2009)
Authors include “diabetes mellitus” as an absolute contraindication. (Source of recommendation unclear.)

Amsterdam Forum (2005)
The following guideline was developed: individuals with a history of diabetes or fasting blood glucose >126 mg/dl (7.0 mmol/L) on at least two occasions (or 2-hour glucose with OGTT >200 mg/dl (11.1 mmol/L)) should not donate. (Recommendation based on Evidence-Based, Expert Opinion.)
7. Hereditary Nephritis (Prototype Alport Disease).

**British Transplantation Society (2011)**
The overall risks associated with Alport syndrome are small and the outcomes of transplantation good, therefore Alport syndrome does not contraindicate living donor transplantation. Both the donor and recipient should be counseled regarding the risks of de novo anti-GBM disease. (B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)

X-linked Alport syndrome (XLAS), which is associated with a 5-20% risk of progressive renal impairment and generally considered to prohibit donation.

**SEN ONT (2010)**
There is an absolute contraindication for living donation when the recipient has diseases with a high risk of aggressive relapse in the grafts: - Early development of glomerulonephritis due to anti-glomerular basement membrane antibodies in patients with Alport’s syndrome.
8. Hematuria.

UNOS (2013)
Aside from including it in a list of kidney specific disease history characteristics to be gathered as part of a patient’s general history, no recommendations identified (Search terms included: Hematuria, haematuria). (Source of recommendation unclear.)

ERBP (2013)
- We recommend considering persistent haematuria of glomerular origin as a contraindication to living donation, because it may indicate kidney disease in the donor. (1B)
- However, we acknowledge thin basement membrane disease might be an exception. (Ungraded statement)

British Transplantation Society (2011)
- All potential living donors should have reagent strip (dipstick) urinalysis performed on at least 2 separate occasions (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Two or more positive tests, including trace positive, should be considered as persistent non-visible haematuria (PNVH) (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- If PNVH is present, perform urine culture and renal imaging to exclude common urologic causes including infection, nephrolithiasis and urothelial carcinoma. (A1: Recommendation made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)
- If no cause is found, perform cystoscopy in patients age >40 years to exclude bladder pathology (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- If no cause is found and the donor still wishes to donate, then a kidney biopsy should be considered, and is recommended if haematuria is >1+ on dipstick testing. (B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)
- Glomerular pathology precludes donation, with the possible exception of thin basement membrane disease (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

CARI (2010)
- The discovery of microscopic haematuria in potential donors needs further investigation to determine if this is clinically significant. Underlying urological and renal disease should be excluded before proceeding to donation. No recommendations regarding potential donors with thin basement membrane disease (TBMD) can be made. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

WHAT DO THE OTHER GUIDELINES SAY? [CARI lists other guidelines]

British Transplant Society / British Renal Association
An extensive, 100-page document has been produced outlining similar issues to those discussed here. The full version of these British Live Donor Guidelines is available at: www.bts.org.uk and at www.renal.org

• Persistent microscopic haematuria in the potential living donor requires full investigation to identify an underlying cause, up to and including renal biopsy if there is no obvious urological explanation. Where there is insufficient evidence to quantify the risks following histological diagnoses of renal pathology, donation is not recommended.
• Advice from a clinical geneticist is recommended when a diagnosis of thin membrane disease is made as new data is being generated all the time.

The Amsterdam Forum:
A short manuscript outlining similar issues to those discussed here. Isolated microscopic hematuria (defined as 3–5 urinary sediment red blood cells (RBCs)/HPF) may not be a contraindication to donation. RBCs with glomerular origin have a dysmorphic appearance observed by phase-contrast microscopy and automated RBC analysis. Patients with persistent microscopic hematuria should not be considered for kidney donation unless urine cytology and a complete urologic work up are performed. If urological malignancy and stone disease are excluded, a kidney biopsy may be indicated to rule out glomerular pathology such as IgA nephropathy.

European Renal Association-European Dialysis and Transplant Association:
(Nephrol Dial Transplant 2000): Exclusion criteria include: 'reduced GFR (in comparison to normal range for age), proteinuria >300 mg/day, microhematuria (except when a urologic evaluation and possible kidney biopsy are normal), or hypertension without good control'.

SEN ONT (2010)
• A microhaematuria (>3 red blood cells/field or 5 red blood cells x106/l) means that lithiasis or microlithiasis must be studied (as can be seen below), and urinary cancer must be ruled out by an extensive urological study (cytology, imaging tests or cystoscopy if needed).
• A kidney biopsy will be needed if there is a possibility that the haematuria is caused by a glomerular disorder (dysmorphic red blood cells)38 glomerulopathies (IgA/IgM nephropathy, Alport's syndrome, thin membrane), medullary sponge kidney and significant glomerulosclerosis.
• Renal function of family members must be studied in great depth when the recipient has hereditary diseases, including a biopsy in certain cases: 1. Alport’s Syndrome: hearing and eye tests. Donation can be considered in men >20 years old and women without haematuria, although the risk of developing kidney damage cannot be completely ruled out without performing a genetic study or electron microscopy.

EAU (2009)
Authors include “microscopic haematuria” as an absolute contraindication. (Source of recommendation unclear.)
UNOS (2013)
Aside from including it in a list of kidney specific disease history characteristics to be gathered as part of a patient’s general history, no recommendations identified (Search terms included: proteinuria). (Source of recommendation unclear.)

ERBP (2013)
- We recommend quantifying urinary protein excretion in all potential living donors. (1C)
- We recommend overt proteinuria is a contraindication for living donation [24-h total protein >300 mg or spot urinary albumin to creatinine (mg/g) ratio >300 (>30 mg/mmol)]. (1C)
- We recommend further evaluating potential living donors with persistent (more than three measurements with 3 months interval) proteinuria <300 mg/24 h by the quantification of micro-albuminuria to assess their risk of living donation. (Ungraded statement)
- We suggest considering persistent (more than three measurements with 3 months interval) micro-albuminuria (30–300 mg/24 h) a high risk for donation. (Ungraded statement)

British Transplantation Society (2011)
- Urine protein excretion should be quantified in all potential living donors (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- A urine albumin/creatinine ratio (ACR) performed on a spot urine sample voided after waking is the recommended screening test, although both urine protein/creatinine ratio (PCR) and 24-hour urine protein collection are acceptable alternatives. (A1: Recommendation made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)
- Significant proteinuria is an ACR >30 mg/mmol, PCR >50 mg/mmol or 24-hour total protein >300 mg/day, and usually contraindicates donation (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- The significance of microalbuminuria (ACR 3.5-30 mg/mmol) and of 24-hour urine protein of 150-300 mg (PCR 15-30) has not been fully evaluated in living kidney donors. However, since both the risk of CKD and cardiovascular morbidity increase progressively with increasing albuminuria, such donors require careful evaluation and counselling about the risks of donation (C2 – Recommendation is based on low quality evidence. Strength of evidence has been indicated at a “we suggest” level.)

CARI (2010)
- Potential living donors should have their urinary protein excretion measured using either a 24-hour urine collection (daily excretion) or a spot urine sample (protein/creatinine ratio). (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)
- A urine protein excretion of >300 mg/day (24 hour collection) or of >30 mg/mmol (spot urine protein/creatinine ratio) is usually a contraindication to live donation. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)
Further investigations are warranted when urine protein excretion is >150 mg/day but less than <300 mg/day (corresponds approximately with spot urinary protein/creatinine of >15 mg/mmol but <30 mg/mmol). Repeat urinary protein estimation, as well as measurement of urinary albumin excretion may help in further assessing potential living donors. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

Although overt proteinuria may be absent, the presence of microalbuminuria (urinary albumin excretion of >30 mg/day or >20 mg/min; albumin/creatinine ratio >2.5 mg/mmol) should be considered a relative contraindication to live donation. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

Microalbuminuria or mild proteinuria (<300 mg/day) occurring in the presence of another associated clinical or laboratory abnormality (e.g. hypertension, obesity, glucose intolerance, glomerular haematuria) should be considered a relative contraindication to live donation. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

In potential living donors with minor degrees of proteinuria or albuminuria, a renal biopsy may help in further assessing the donor’s risk of developing progressive renal disease following donation. (Recommendation is based on Expert Opinion.)

Donors should have their urinary protein excretion measured as part of their routine, follow-up care. It is recommended that this be performed at least once a year along with blood pressure and serum creatinine measurement. (Recommendation is based on Expert Opinion.)

WHAT DO THE OTHER GUIDELINES SAY? [CARI lists other guidelines]

- A 24 hour urine protein of >300 mg is a contraindication to donation.
- Microalbuminuria determination may be a more reliable marker of renal disease, but its value as an international standard of evaluation for kidney donors has not been determined.

The Canadian Council for Donation and Transplantation (2006):
We recommend . . . to refer to existing guidelines regarding the assessment and eligibility of potential living kidney donors (e.g. Amsterdam Forum).

European Renal Association-European Dialysis and Transplant Association (2000):
Exclusion criteria of donor proteinuria >300 mg/day.

UK Guidelines for Living Donor Kidney Transplantation (2005):
The presence of proteinuria is a strong independent predictor of future end stage renal disease in the general population. Urine protein excretion should be quantified by analysis of a 24-hour urine collection or spot urine protein : creatinine ratio. Increased urine protein excretion usually excludes further consideration as a kidney donor.

The following reasons will typically exclude a living donor candidate from donating . . . 3300 mg/day of proteinuria.
SEN ONT (2010)
- A proteinuria >300mg/day rules out donation.
- Measurement of 24-hour proteinuria and microalbuminuria (the measurement of protein/creatinine ratios in isolated samples is not acceptable11) and urinary sediment

EAU (2009)
Authors include “proteinuria (>300 mg/24h)” as an absolute contraindication to donation. (Source of recommendation unclear.)
10. Gestational Diabetes

**UNOS (2013)**
Aside from including it in a list of kidney specific disease history characteristics to be gathered as part of a patient’s general history, no recommendations identified (Search terms included: gestational diabetes). *(Source of recommendation unclear.)*

**British Transplantation Society (2011)**
If there is a history of transient gestational diabetes, the lifetime risk of Type 2 diabetes is very high (16,17) and kidney donation is relatively contraindicated.

**SEN ONT (2010)**
Previous history of gestational diabetes is an absolute contraindication to donation given the high rate of developing diabetes later in life.
UNOS (2013)
Authors suggest a lipid profile as one of a number of metabolic tests to be completed as a part of the Medical Evaluation of the Living Donor. No other recommendation is made (Search terms included: lipid profile, lipid). *(Source of recommendation unclear.)*
13. Managing Smoking Prior to Donation

UNOS (2013)
Other than recommending assessments for smoking, authors make no recommendation regarding the management of smoking prior to donation (Search terms included: smoking). (Source of recommendation unclear.)

ERBP (2013)
- We recommend patients stop smoking before transplantation. (1B)
- Smoking cessation programmes should be offered. (Ungraded Statement)

British Transplantation Society (2011)
Living kidney donors should be encouraged to minimize the risk of hypertension and its consequences by lifestyle measures including smoking cessation, frequent exercise and, where appropriate, weight loss. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

SENONT (2010)
Tobacco smoking and excessive alcohol consumption (>60g/day) may justify the need for further tests and increase the risk of postsurgical complications in general. It is strongly recommended that these habits are stopped completely at least 4 weeks before the operation. It must be stressed that these habits must be stopped definitively, given that smoking increases the donor’s risk of death in the long term.

Amsterdam Forum (2005)
Smoking cessation at least 4 weeks prior to donation is advised, based on recommendations for patients undergoing elective surgical procedures. (Recommendation based on Evidence-Based, Expert Opinion.)

NKF/AST (Abecassis, 2000)
While donors with no smoking history are preferable, smokers can be considered if they are tobacco free for 6 months prior to donations and have normal results for pulmonary studies. (Source of recommendation unclear.)
UNOS (2013)
Other than recommending BMI be collected as a part of the physical exam for potential donors, no recommendation regarding safe pre-donation BMI is identified. (Search terms included: BMI.) (Source of recommendation unclear.)

ERBP (2013)
- We suggest a BMI >35 kg/m² is a contraindication to donation. (2C)
- We recommend counselling obese and overweight donors for weight loss before and after donation. (Ungraded statement)
- We recommend that patients with a body mass index (BMI) >30 kg/m² reduce weight before transplantation. (Ungraded Statement)

British Transplantation Society (2011)
- Otherwise healthy overweight patients (BMI 25-30 kg/m²) may safely proceed to kidney donation. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Moderately obese patients (BMI 30-35 kg/m²) should undergo careful pre-operative evaluation to exclude cardiovascular, respiratory and kidney disease (C1)
- Moderately obese patients (BMI 30-35 kg/m²) should be counselled carefully about the increased risk of peri-operative complications, based on extrapolation of outcome data from very obese donors (BMI > 35 kg/m²). (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Moderately obese patients (BMI 30-35 kg/m²) should be counselled carefully about the long-term risk of kidney disease. They should be advised to lose weight prior to donation and to maintain their ideal weight following donation. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Data on the safety of kidney donation in the very obese (BMI > 35 kg/m²) are limited and such patients should be discouraged from donating (C1)

CARI (2010)
- A combination of waist circumference and body mass index (BMI) is recommended for the clinical assessment of overweight and obesity.1 Consideration of differential risk according to ethnicity should be undertaken. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)
- Obesity (BMI > 30 kg/m²) should be considered a relative contraindication to donation. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

What do the other guidelines say? [CARI lists other guidelines]

• All living donors should have BMI determined at baseline evaluation and obesity should be considered an increased risk for renal disease, acknowledging that there are no data on which to base a firm recommendation.
• Patients with a BMI > 35 kg/m² should be discouraged from donating, especially when other comorbid conditions are present.
• Obese patients should be encouraged to lose weight prior to kidney donation and should be advised not to donate if they have other associated comorbid conditions.
• Obese patients should be informed of both acute and long-term risks, especially when other comorbid conditions are present. S126 The CARI Guidelines
• Healthy lifestyle education should be available to all living donors.

There is debate regarding the eligibility of those with . . . donor BMI > 35. Little is known about either the longterm risks to such donors or the long-term outcome of kidneys from such donors.

European Renal Association-European Dialysis and Transplant Association (2000)
No recommendation.

UK Guidelines for Living Donor Kidney Transplantation (2005)
A BMI of more than 35 kg/m² should be regarded as an absolute contraindication to kidney donation and a BMI of more than 30 kg/m² is a relative contraindication. Obese patients with a BMI greater than 30 kg/m² should undergo careful pre-operative evaluation to exclude cardiovascular, respiratory and renal disease. They should be counseled regarding the increased perioperative risk and potential long-term risk of renal disease and advised to lose weight prior to donation and encouraged to achieve their ideal weight following donation.

Morbid obesity is an exclusion criterion.

SENONT (2010)
• Severe obesity (BMI>35) is a contraindication to donation, as it is associated with a greater surgical risk and greater risk of developing CKD in the long term.
• Obesity (BMI=30-35 or waistline >82cm in women or >102cm in men) may also be a contraindication if it is associated with other risk factors such as HBP, abnormal baseline glycaemia or family history of this condition and microalbuminuria.

EAU (2009)
Authors include “obesity” as a relative contraindication. (Source of recommendation unclear.)

Amsterdam Forum (2005)
The following consensus guidelines were adopted regarding obesity:
• Patients with a BMI >35 kg/m² should be discouraged from donating, especially when other comorbid conditions are present.
• Obese patients should be encouraged to lose weight prior to kidney donation and should be advised not to donate if they have other associated comorbid conditions.
• Obese patients should be informed of both acute and long-term risks, especially when other comorbid conditions are present.
• Healthy lifestyle education should be available to all living donors. (Recommendation based on Evidence-Based, Expert Opinion.)

NKF/AST (2000)
The potential donor should not be more than 25% above ideal body weight due to both health concerns for the donor and technical considerations for the donor surgery. (Source of recommendation unclear.)
15. Cardiovascular Risk profile assessment (re: hypertension, diabetes, lipid profile, smoking, BMI)

UNOS (2013)
Authors recommend potential donors be evaluated for a personal history of significant medical conditions which include but are not limited to hypertension, diabetes, genetic renal diseases, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer and history of infections. (Source of recommendation unclear.)

EBPG (2013)
- We recommend that basic clinical data, physical examination, resting electrocardiogram (ECG) and chest X-ray are a sufficient standard work-up in asymptomatic low-risk kidney transplant candidates. (1C)
- We recommend performing a standard exercise tolerance test and cardiac ultrasound in asymptomatic high-risk patients (older age, diabetes, history of cardiovascular disease). In patients with a negative test, further cardiac screening is not indicated. (1C)
- We recommend performing further cardiac investigation for occult coronary artery disease with non-invasive stress imaging (dobutamine stress echocardiography or myocardial perfusion scintigraphy) in kidney transplant candidates with high risk and a positive or inconclusive exercise tolerance test. (1C)
- We recommend performing coronary angiography in kidney transplant candidates with a positive test for cardiac ischaemia. Further management should be according to the current cardiovascular guidelines. (1D)

British Transplantation Society (2011)
Authors include “Cardiovascular risk factors in their list of “Points of particular importance in the medical history of a potential kidney donor.”

SEN ONT (2010)
Authors include both an ECG and chest x-ray in their list of recommended tests for pre-donation assessment.

EAU (2009)
Authors include “heart disease” as a “Medically significant illness” and an absolute contraindication for donation. No recommendations for testing are included. (Source of recommendation unclear.)
16. Racial / Ethnic Considerations

British Transplantation Society (2011)
Prospective donors with an increased risk of Type 2 diabetes because of family history, ethnicity or obesity should also undergo an OGTT (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
UNOS (2013)
Donor age <18 is a contraindication. (Source of recommendation unclear.)

ERBP (2013)
We recommend that old age in itself is not a contraindication to donation. (1B)

British Transplantation Society (2011)
- Old age alone is not an absolute contraindication to donation but the medical work-up of older donors must be particularly rigorous to ensure they are suitable (A1)
- Both donor and recipient should be made aware that the older donor may be at greater risk of peri-operative complications and that the function and possibly the long-term survival of the graft may be compromised. This is particularly evident with donors >60 years of age (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Children (age <18) should only be considered as living organ donors in exceptionally rare circumstances.
- Initial assessment of donor and recipient histocompatibility status should be undertaken at an early stage in living donor kidney transplant workup to avoid unnecessary and invasive clinical investigations. (B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)
- Screening of potential living donor kidney transplant recipients for clinically relevant antibodies is important for ensuring optimal donor selection and graft survival. (A1: Recommendation made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)
- Transplant units and histocompatibility laboratories should agree an evidence-based protocol to define crossmatch results which constitute a veto to transplantation. (B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)
- A pre-transplant serum sample collected within 14 days of the planned date for transplantation must be tested in a sensitive crossmatch and if the crossmatch test is positive transplantation should not usually be performed, unless the antibody is shown to be indicative of acceptable immunological risk (A1)
- Changes in immunosuppression during the transplant work-up should be notified to the histocompatibility laboratory and additional antibody screening and donor-recipient crossmatch tests undertaken as required. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- HLA matching should be considered of benefit when there is an option of selecting between living donors, particularly in reducing the possibility of subsequent sensitisation. This is important for younger recipients where repeat transplantation may be required. However, it is recognised that other donor factors will be taken into account. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- The histocompatibility laboratory should issue an interpretive report stating the donor and recipient HLA mismatch, recipient sensitisation status and crossmatch results, and define the associated immunological risk for all living donor-recipient pairs. (A1: Recommendation
made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)

**SEN ONT (2010)**

- The **minimum age for donation is 18 years in Spain**. It is particularly important to assess if very young donors are mature enough to make their own decisions.
- There is no set maximum age limit (although donation is rarely considered in patients over 70 years old in Spain).
- Recipients and donors should be typed at least for HLA-A, HLA-B and HLA-DRB1 at the antigen level (first two or three digits). DNA-based HLA-typing techniques for DNA are highly recommended for their reliability and reproducibility.
- For HLA-A and HLA-B typing, serology may be acceptable.
- If anti-HLA-C, HLA-DQ or HLA-DP antibodies have been identified in the recipient, then it may be useful to expand donor typing to these loci (see virtual crossmatch)
- Allelic typing of the donor (four or more digits) may be indicated in special cases where there are antibodies against only some alleles (4 digits) of the same antigen group (2 digits) (for example, A2402 positive, A2403 negative).

**EAU (2009)**

Age <18 years and ABO incompatibility, and are included in the list of absolute contraindications. *(Source of recommendation unclear.)*

**NKF/AST (Abecassis, 2000)**

Although minors (individuals younger than 18 years) have successfully donated kidneys to family members in rare instances, using a minor as a live donor remains controversial and requires careful donor consideration. However, exceptional circumstances that would permit the ethical use of a minor as a live donor were established by the conference attendees.

Conditions in Which a Minor May Ethically Act as a Live Organ Donor:

- When the potential donor and recipient are both highly likely to benefit (as in the case of identical twins).
- When the surgical risk for the donor is extremely low.
- When all other opportunities for transplantation have been exhausted, no potential adult living donor is available and timely and/or effective transplantation from a cadaver donor is unlikely.
- When the minor freely agrees to donate without coercion (established by the independent donor advocate). *(Source of recommendation unclear.)*
18. Kidney Biopsy Indications

**British Transplantation Society (2011)**
- If no cause (for non-visible haematuria) is found and the donor still wishes to donate, then a kidney biopsy should be considered, and is recommended if haematuria is >1+ on dipstick testing. *(B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)*

**SEN ONT (2010)**
- Related donors must be assessed carefully, and a preliminary kidney biopsy may be necessary to discard familial kidney diseases that may have gone unnoticed (e.g. some cases of IgA nephropathy).
- A kidney biopsy will be needed if there is a possibility that the haematuria is caused by a glomerular disorder (dysmorphic red blood cells)38 glomerulopathies (IgA/IgM nephropathy, Alport's syndrome, thin membrane), medullary sponge kidney and significant glomerulosclerosis
- If leukocyturia cannot be explained by an infection, a kidney biopsy may be needed to rule out interstitial nephritis or chronic pyelonephritis (which would also rule out donation).
- If there is no family history of polycystic disease (PC), the presence of a small, isolated cyst (<1cm) is not an obstacle for donation. Larger isolated simple cysts can also be allowed (up to 5cm, Bosniak category 1), although the surgeon may decide to perform a kidney biopsy with excision and closure
UNOS (2013)
Authors recommend potential donors be evaluated for a personal history of significant medical conditions which include but are not limited to hypertension, diabetes, genetic renal diseases, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer and history of infections. *(Source of recommendation unclear.)*

British Transplantation Society (2011)
Points of particular importance in the medical history of a potential kidney donor:
- Haematuria/proteinuria/urinary tract infection
- History of peripheral oedema
- Gout
- Nephrolithiasis
- Hypertension
- Diabetes mellitus, including family history
- Ischaemic heart disease/peripheral vascular disease/other atherosclerosis
- Cardiovascular risk factors
- Thromboembolic disease
- Sickle cell and other haemoglobinopathies
- Weight change
- Change in bowel habit
- Previous jaundice
- Previous malignancy
- Systemic disease which may involve the kidney
- Chronic infection such as tuberculosis
- Family history of a renal condition that may affect the donor
- Smoking
- Current or prior alcohol or drug dependence
- Psychiatric history
- Obstetric history
- Residence abroad
- Previous medical assessment e.g. for life insurance
- Previous anaesthetic problem
- History of back or neck pain and trauma
- Results of national screening programme tests e.g. cervical smear, mammography, colorectal screening. *(Source of recommendation unclear.)*

SEN ONT (2010)
Authors recommend the following pre-donation assessment:
- General laboratory tests*
- Oral glucose overload test, if applicable
- ABO blood typing
- ECG
- Chest x-ray
- Abdominal ultrasound
- HLA typing. First crossmatch-immunological study of the recipient
- Special studies, if applicable at this time: cardiology, respiratory, etc.

*Minimum laboratory tests include:
  Blood:
  - General biochemical test: glucose, urea, creatinine, sodium, potassium, calcium, phosphorus, uric acid, blood gases
  - Haemogram,
  - Blood coagulation test,
  - Iron metabolism
  - Liver biochemical tests
  - Proteinogram-Immunoglobulins
  - Lipids
  - HbA1c
  - Serology (see Table 3)
  - PSA (men >40 years old)
  - Pregnancy test, where applicable
  - Oral glucose overload test, if applicable
  Urine:
  - Basic urine test, twice
  - 24-hour urine test (creatinine clearance, calciuria, proteinuria, microalbuminuria), twice
  - Urine culture
  - Löwenstein Medium Culture

EAU (2009)
It is the surgeon's responsibility to ensure that the donor is medically, as well as psychologically, suitable for the procedure; the donated organ is healthy; and the expectation of success in the recipient is reasonable. (Grade of recommendation: B, Based on well-conducted clinical studies, but without randomized clinical trials.)
**20. Peri-Operative assessment: Imaging test, Kidney anatomy, multiple vessels**

**EAU (2009)**

The only reference authors made to this question were, “multiple renal artery or grafts with anatomical anomalies are not absolute contraindications. Decisions should be made on an individual basis. (Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)
21. Surgical Approach – Laparoscopic vs. Open

ERBP (2013)
For living donor nephrectomy, we suggest either a minimally invasive or laparoscopic approach rather than a flank subcostal retroperitoneal one. The choice between minimal invasive and laparoscopic procedure should be based on the local expertise. (2C)

BTS (2011)
Laparoscopic donor surgery is the preferred technique for living donor nephrectomy, offering a quicker recovery, shorter hospital stay and less pain. Mini-incision surgery is preferable to standard open surgery. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

CARI (2010)
• Donor mortality and major complications appear equivalent with laparoscopic and open donor nephrectomy. In open surgery, the risks appear related to perioperative complications including pulmonary emboli, pneumonia and ischaemic events. With laparoscopic surgery, complications are largely due to catastrophic intraoperative events related to securing of the vascular pedicle. Measures to reduce these specific problems should be undertaken and tailored to the technique used by individual transplant units. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)
• Use of a non-transfixing mechanism for securing the renal artery is not recommended, particularly with laparoscopic donor nephrectomy.
• Laparoscopic donor nephrectomy is more resource intensive, but may offer advantages to many donors: (Recommendation based on Level III and IV evidence.)
  – Increased operative time but equivalent hospitalization (based on hospital stay in five out of six randomized controlled trials) with laparoscopic compared with open donor nephrectomy
  – Reduced analgesic requirements and return to normal activities with laparoscopic donor nephrectomy compared with open surgery.
• Death and major complications occur infrequently following donor nephrectomy. This limits the feasibility of randomized controlled trials comparing donor surgical techniques. The best available evidence will evolve over time with comprehensive registry data. (Recommendation based on Level II evidence.)

What Do Other Guidelines Say? [CARI lists other guidelines]
Kidney Disease Outcomes Quality Initiative: No recommendation.
UK Renal Association: No recommendation.
British Transplant Society: No recommendation.
Canadian Society of Nephrology: No recommendation.
European Best Practice Guidelines: No recommendation.
Amsterdam Forum: Care of the live kidney donor
There are no guidelines available for surgical technique in living donor nephrectomy. In relation to DVT prophylaxis, factor v-leiden, a variant of the coagulation protein factor v, is associated with venous thrombosis, especially in oral contraceptive users. It is the most common hereditary blood coagulation disorder and is present in 3–8% of the healthy white population. Factor v-leiden mutant genes have been detected in 2% of living donors. The odds ratio of a venous thrombo-embolic event is 11 times greater in women taking oral contraceptives who
have factor v-leiden mutation than those who do not. It is recommended that a history of venous thromboembolism be ascertained prior to an in-depth coagulation work-up. Unless the medical history reveals a medical concern that would necessitate a comprehensive coagulation profile, tests are considered not likely to yield information. Such tests include PT, PTT, antithrombin 3, protein S, Protein C, Activated protein C resistance (APC), PT-Prothrombin mutation, cardiolipin antibodies and lupus anticoagulants. It is recommended that oral contraceptives and hormone replacement therapy be withheld for 3 months prior to donation.

**SEN ONT (2010)**
Laparoscopic living donor nephrectomy has shown less morbidity than the open approach, with less pain and analgesia requirements and allowing a quicker recovery and an earlier return to normal activity. Furthermore, many studies have shown equivalent results between both approaches in terms of graft function and recipient complications. For these reasons, we can accept laparoscopic kidney living donor nephrectomy as the gold standard surgical technique in these patients. The implementation of this minimally invasive technique in most centers has led to an increase in the rate of this kind of organ procurement, due to its better acceptance by the donors.

**EAU (2009)**
Laparoscopic nephrectomy offers equal urological complications, graft function and graft survival than open nephrectomy, with less post-operative morbidity, shorter convalescence and better cosmetic results. *(Grade of recommendation: A, Based on clinical studies of good quality and consistency addressing the specific recommendation and including at least one randomised trial.)*

**JSE (2009)**
Although there is, at present, no high-level evidence, laparoscopic living donor nephrectomy is considered less invasive than open surgery. Many studies have reported that operative times are long compared with open procedures, although this difference can be reduced with improved operator proficiency. Most studies reported no difference in function of the transplanted kidney in the recipient between laparoscopic and open surgery, however the follow-up period was not long enough for comparing graft function in each procedure. Although most reports stated the complication rate was not significantly different in open and laparoscopic donor nephrectomy, the UNOS report, with large patient numbers, found a significantly lower complication rate in the open surgery group. Thorough attention should be given to the possibility of complications when performing laparoscopic living donor nephrectomy.

From the above, laparoscopic living donor nephrectomy is a minimally invasive surgical modality that should be performed by a surgeon experienced in laparoscopic surgery and transplant medicine. The American UNOS survey identified two deaths and one patient left in a vegetative state out of 5168 patients undergoing laparoscopic living donor nephrectomy. In Japan, this procedure should be performed by surgeons experienced in laparoscopic renal surgery and well versed in open living donor nephrectomy. Alternatively, surgeons experienced in the above-mentioned different surgical modalities could form a nephrectomy team. Institutions commencing laparoscopic living donor nephrectomy should do so under the direction of an accredited laparoscopist. Before performing this procedure, the surgeon should explain to the donor and their family the advantages
and disadvantages of laparoscopic living donor nephrectomy, possible complications, the deaths reported from the USA, and the possibility of conversion to an open procedure, and obtain informed consent. (Recommendation based on one prospective RCT of hand-assisted lap and open.)
ERBP (2013)
Under which conditions can HIV infected patients be enrolled on the waiting list:
- We recommend that HIV per se is not a contraindication for kidney transplantation. (1C)
- We recommend waitlisting HIV patients only if
  (1) they are compliant with treatment, particularly HAART therapy
  (2) their CD4+ T cell counts are >200/μL and have been stable during the previous 3 months
  (3) HIV RNA was undetectable during the previous 3 months
  (4) no opportunistic infections occurred during the previous 6 months
  (5) they show no signs compatible with progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis or lymphoma. (1C)
- We suggest that the most appropriate anti-retroviral therapy should be discussed before transplantation with the infectious diseases team in order to anticipate potential drug interactions after transplantation. (Ungraded Statement)

Is there a role for immunization against herpes varicella-zoster prior to kidney transplantation?
- We recommend immunization against varicella-zoster virus in all paediatric and adult patients negative for antivaricella- zoster antibodies, preferably when they are still waitlisted.

UNOS (2013)
Infectious disease testing must include:
- CMV (Cytomegalovirus) Antibody
- EBV (Epstein Barr Virus) Antibody
- HIV 1,2 (Human Immunodeficiency Virus) antibody testing
- HepBsAg (Hepatitis B surface antigen)
- HepBcAB (Hepatitis B core antibody)
- HepBsAB (Hepatitis B surface antibody)
- HCV (Hepatitis C Virus) antibody testing
- RPR (Rapid Plasma Reagin Test for Syphilis)

For tuberculosis (TB), living donor recovery centers must determine if the potential donor is at increased risk for this infection, and if so testing must include:
- Screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA)

For the following infectious diseases, transplant centers must determine if the potential donor is from an endemic area, and if so testing must include:
- Strongyloides
- Trypanosoma cruzi
- West Nile (Source of recommendation unclear.)

British Transplantation Society (2011)
- Infection screening in the prospective donor prior to donation is important to identify potential risks for the donor from previous or current infection and to assess the risks of transmission of infection to the recipient. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Active HBV and HCV infection in the donor are usually contraindications to living donor kidney transplantation; however, donors with no evidence of active viral replication may be considered under some circumstances. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

- The CMV status of donor and recipient should be determined before transplantation. When the donor is CMV positive and the recipient is CMV negative, the donor and recipient should be counselled about the risk of post-transplant CMV. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

- The EBV status of donor and recipient should be determined before transplantation. When the donor is EBV positive and the recipient is EBV negative, the donor and recipient should be counselled about the risk of developing PTLD. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

- The presence of HIV or human T lymphotrophic virus (HTLV) infection is an absolute contraindication to living donation. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

**SEN ONT (2010)**

Authors recommend the following testing:

**Detecting Infections:**
Tuberculosis skin test (PPD) (b)

Serology:
- Human immunodeficiency virus (HIV) (a)
- Hepatitis B: HBV-surface antigen (HBsAg) (a)
- HBV-core antigen (HBcAb IgM/IgG) (b)
- HBV-surface antibody (HBsAb)
- DNA-HBV in plasma if HbcAb positive
- Hepatitis C (ELISA and PCR) (a)
- Cytomegalovirus (CMV IgC/IgM) (b)
- Epstein-Barr (EBV IgG/IgM) (b)
- Toxoplasma test
- Syphilis: RPR (rapid plasma reagin)-FTA (b)
- Brucella (b)

Optional (depending on where the donor is from):
- Human T-lymphotropic virus-HTLV I-II (a)
- Trypanosoma cruzi-Chagas disease (b)
- Strongyloides (b)
- Malaria
- Schistosomiasis (b)
- Coccidiomycosis, histoplasmosis

(a) Donation is contraindicated with positive results
(b) Donors and/or recipient have to undergo treatment with positive results.

**EAU (2009)**

Any donor organ affected by a potentially transmittable pathology (infections, neoplasias) must be
carefully evaluated considering the risk-benefit ratio for the recipient. (Grade of recommendation: A, Based on clinical studies of good quality and consistency addressing the specific recommendation and including at least one randomised trial.)

There is a high risk of HIV transmission from potential donors with suspected intravenous drug abuse. In addition, serology tests during the incubation period of HIV (2 months) or hepatitis (up to 6 months) may be negative, while large amounts of fluids administered during a resuscitation attempt can result in a normal serology due to dilution effects. Serological tests must therefore be repeated and additional tests done (e.g., polymerase chain reaction) to rule out infection.

Authors list “Active chronic infection (e.g., tuberculosis, hepatitis B/C, parasites)” as a relative contraindication for living donors. (No clear rationale for recommendation.)

**Amsterdam Forum (2005)**

**HIV**
The detection of a positive human immunodeficiency virus (HIV-1 and HIV-2) by an ELISA assay for both antigen and antibody in a potential kidney donor should be confirmed by a neutralization test and a western blot analysis. The positive result rules out an individual from being a live kidney donor.

**CMV and EBV**
Despite these efforts, the importance and success of a live donor parental transplant was sufficient to not prohibit the use of a CMV or EBV positive donor for a recipient who is CMV or EBV negative.

**Hepatitis C Virus**
If the donor has normal liver function tests and the serology test for hepatitis C virus (HCV) is negative (nonreactive antibody determination by ELISA), there is no contraindication for donation. However, if the serology test is positive for HCV, Essam Elsawy recommended that the recipient HCV status be evaluated. If the potential recipient is negative for HCV, the potential positive HCV donor should be excluded. If the potential recipient is also positive for HCV, the potential donor should be assessed by PCR for HCV. If the potential donor is PCR positive, the potential donor should be excluded because of the risk of HCV transmission to the recipient and because the potential donor may have chronic hepatitis (and is not well). If the potential donor is negative by PCR, the potential donor may not necessarily be excluded because the likelihood of transmission of HCV through the kidney is remote. Nevertheless, Jose Morales expressed concern regarding HCV superinfection if a different HCV genotype of a positive donor is transmitted to a recipient. The Spanish group has transplanted kidneys from deceased donors with HCV reactivity to HCV positive recipients, but they have not performed live kidney transplantation from HCV positive donors. Further, Chakko Jacob and Nabil Mohsin questioned the justification of removing a kidney from a patient who in the future may develop an HCV-associated renal disease. However, Stephen Munn suggested that if certain HCV genotypes (genotype 4) are treated and eradicated in the donor, the potential donor could be reconsidered (if no evidence of chronic hepatitis or cirrhosis on biopsy).

**Hepatitis B Virus**
The detection of hepatitis B surface antigen (HBsAg) in a potential donor generally excludes the individual from live kidney donation. However, Stephen Munn reported that in New Zealand, some of the live kidney donors have been hepatitis B virus (HBV) core antibody positive. An IgM core positive result indicates a recent exposure to the HBV; in contrast, a surface antibody positive result indicates that months may have elapsed since the hepatitis infection. Even if HBsAg is negative, screening for HBV core total antibody (IgM and IgG) should be done to exclude low-level HBsAg and escape mutants of HBV not detectable by the current screening assays for HBsAg. The ELISA core antibody test can distinguish between IgM and IgG reactivity. If the core antibody result is positive for IgM, a delay in the consideration of the potential donor was recommended to determine whether HBV
infection might be progressing. A PCR quantitation of HBV DNA should be performed as appropriate care of the donor. Otherwise, by the New Zealand practice, if the potential donor is PCR negative for HBV, kidneys may be transplanted safely from either an HBV surface antibody positive donor or a donor who is HBV core antibody (IgG) positive into recipients who either have successfully recovered from hepatitis B infection or been immunized against hepatitis B.

**Human Herpes Virus 8**

Human Herpes Virus 8 (HHV8) has been shown to induce Kaposi sarcoma and can be transmitted by organ transplantation.

**Tuberculosis**

Active *Mycobacterium tuberculosis* infection is a contraindication for donation because tuberculosis has been transmitted from live kidney donors to their recipients.

**Syphilis**

Donors should be screened for syphilis (*Treponema pallidum*) with the rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL) slide test. The RPR and the older VDRL test detect reactive antibodies. There are several conditions that may cause a false positive test: HIV, Lyme disease, mycoplasma pneumonia, malaria, and systemic lupus erythematosus. Therefore, these screening tests, if found to be positive, must be confirmed by a more specific test for syphilis such as a fluorescent treponemal antibody (FTA) absorption test. Donors with a positive confirmatory FTA should be treated according to stage and donation should bedelayed until successful treatment is accomplished. There may be a risk of syphilis transmission if the donor is untreated. The recipient could receive treatment following transplantation, if there is an urgent need to perform transplant. Secondary syphilis is associated with reversible renal disease.

**Chagas Disease**

Donors from endemic areas should be screened by serologic tests (there are at least three of them). A complement fixation test (Machado-Guerreiro reaction) becomes positive in the acute stage at one month postinfection and remains positive thereafter. The Machado-Guerreiro has a low sensitivity and specificity that yields high incidence of false positives and negatives. The precipitin test (hemagglutination reaction) is 95% positive in the early stages. The immunofluorescence and ELISA tests are highly sensitive and specific, although false-positive reactions occur with malaria, leprosy, and leishmaniasis. If two of the screening tests are positive, the detection of the trypanosome should be ruled out in the blood by a xenodiagnostic test that entails the following: uninfected laboratory-raised insects are fed on a patient, and then examined 30 days later for metacyclic trypanosomes in their hindgut or feces. If positive, the potential donor must be treated and cannot donate until parasitemia turns negative. The Forum participants concluded that donors with positive serology for Chagas disease should not be excluded.

**Schistosomiasis**

If there is active schistosomiasis in an otherwise healthy donor, the donor is treated at least one month before transplantation by combined antischistosomal drugs (praziquantel and oxamniquine). Cure without impairing renal function has been observed without a negative impact on the transplant outcome.

**Strongyloides**

The presence of nematode larvae in a fecal sample is characteristic of strongyloidiasis; however, an ELISA assay is available for serological detection of strongyloides. Potential donors should be screened for strongyloides in endemic areas because strongyloides has been transmitted via a kidney transplant.

**Brucellosis**

Brucellosis has been transmitted to recipients of bone marrow transplants. It was suggested that a patient successfully treated for brucellosis infection may still be a suitable live kidney donor.

**Malaria**
Potential live kidney donors who either reside or have traveled to endemic areas should be screened for *Plasmodium falciparum*. *(Recommendation based on Evidence-Based, Expert Opinion.)*
UNOS (2013)
Centers must develop protocols consistent with the American Cancer Society (ACS), and once
developed follow their own protocols for screening:
• Cervical Cancer
• Breast Cancer
• Prostate Cancer
• Colon Cancer
• Skin Cancer
• Lung cancer

Transplant programs that perform living kidney donor recoveries must exclude all donors who meet
any of the following exclusion criteria: Active malignancy, or incompletely treated malignancy

UNOS recommends an HCG quantitative pregnancy test for premenopausal women without surgical
sterilization.

UNOS recommends an assessment of a patient’s history of smoking, alcohol, and drug use/abuse
and dependency as a part of the Psychosocial Evaluation of the Living Kidney Donor This
psychosocial evaluation must be performed by a psychiatrist, psychologist, and/or clinical social
worker. Documentation of the psychosocial evaluation must be maintained in the donor record.
(Source of recommendation unclear.)

ERBP (2013)
• We recommend that women who drink >40 g and men who drink >60 g of alcohol per day stop or
reduce their alcohol consumption to below these levels. (1D)
• These patients can be waitlisted, but a careful surveillance of reduction of alcohol consumption
should be exerted. (Ungraded Statement)
• We recommend not waitlisting patients with alcohol ‘dependence’. (Ungraded Statement)
• Strategies to stop alcohol consumption should be offered, according to the World Health
Organization (WHO) Clinical Practice Guideline. (Ungraded Statement)
• We recommend not waitlisting patients with an ongoing addiction to ‘hard drugs’ resulting in non-
adherence. (1D)

British Transplantation Society (2011)
Cancer Screening:
• Careful history taking, clinical examination and investigation of potential donors are essential to
exclude occult malignancy prior to kidney donation, particularly in older (age >50 years) donors.
Active malignant disease is a contraindication to living donation, but donors with certain types of
successfully treated low-grade tumour may be considered after careful evaluation and discussion.
(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the
recommendation.)
• Bilateral angiomyolipomata preclude living kidney donation. Kidneys containing lesions of 4 cm or
larger should only be transplanted if ex vivo excision of the tumour is straightforward. Kidneys with
lesions of 1 cm or smaller may be transplanted and followed with serial ultrasound imaging.
Lesions between 1 cm and 4 cm in diameter need to be assessed on a case-by-case basis and the lack of evidence shared with the donor and recipient pair (C1)

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Type of Cancer</th>
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<tbody>
<tr>
<td>Absolute contraindication</td>
<td>Melanoma&lt;br&gt;Testicular cancer&lt;br&gt;Renal cell carcinoma*&lt;br&gt;Choriocarcinoma&lt;br&gt;Haematological malignancy&lt;br&gt;Lung carcinoma&lt;br&gt;Breast cancer&lt;br&gt;Monoclonal gammopathy**</td>
</tr>
<tr>
<td>Possible donation</td>
<td>Treated cancer with high probability of cure after 5-10 years (favourable classification and staging) e.g. colon cancer (Dukes A &gt;5 years ago), non-melanoma skin cancer, carcinoma-in-situ of the cervix or vulva</td>
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Current or prior alcohol or drug dependence is listed as a “point of particular importance in the medical history of a potential kidney donor”.

**CARI (2010)**

Potential female donors of child-bearing age should have a beta-hCG performed prior to further investigations. *(Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)*

**SEN ONT (2010)**

*Amicrohaematuria (>3 red blood cells/field or 5 red blood cells x106/l) means that lithiasis or microlithiasis must be studied (as can be seen below), and urinary cancer must be ruled out by an extensive urological study (cytology, imaging tests or cystoscopy if needed).*

Colon: indicated according to the recommendations for the general population (first-grade family history of the disease, age >50 years old and others). Minimum: *faecal occult blood test. Colonoscopy* is recommended.

Breast: *Mammography/ultrasound* for women >40 years old, or if they have a family history of breast cancer.

Uterus: cervical *cytology* and pelvic ultrasound.

Prostate: *rectal examination and prostate-specific antigen* for men >50 years old, or if there is family history of early prostate cancer.

Specific studies according to the findings of the preliminary study or the donor’s previous or family history; for example: *dermatology exam* if there is family history of melanoma or a high number of
naevus.

*Donation is ruled out if there is a previous diagnosis of* haematological, gastrointestinal, testicular, melanoma, lung, breast, kidney or urinary cancers, choriocarcinoma or monoclonal gammopathy

**EAU (2009)**

A previous history of malignancy is not usually a contraindication for organ donation. However, there are some absolute contraindications that make a donor unsuitable for transplant. These are active cancer or a history of metastatic cancer (with a few exceptions, such as testicular cancer) and cancers with high recurrence rates, such as advanced breast carcinoma, melanoma, leukaemia, or lymphoma. In addition, when a potential donor has experienced a brain haemorrhage of unknown aetiology, metastasis must be excluded as a cause of intracranial bleeding. *(No clear rationale for recommendation.)*

**Amsterdam Forum (2005)**

**Pregnancy**

It was recommended, however, to delay pregnancy until at least 2 months after nephrectomy to assess renal compensation prior to conception with evaluation including blood pressure, GFR, and assessment for microalbuminuria. The emphasis was to verify that postpartum renal function is normal.

**Malignancy:**

Living kidney donors should be screened by standard medical guidelines to exclude malignancy, noting that:

- The risk of clinical and subclinical malignancy increases markedly with age, especially over 50 years.
- The risk of different cancers differs between countries.
- Donors with low-grade nonmelanoma skin cancer may be accepted; otherwise the living kidney donor should be free of current or untreated malignancy.

A prior history of the following malignancies usually excludes live kidney donation:

- Melanoma, testicular cancer, renal cell carcinoma, choriocarcinoma, hematological malignancy, bronchial cancer, breast cancer and monoclonal gammopathy.

A prior history of malignancy may only be acceptable for donation if:

- Prior treatment of the malignancy does not decrease renal reserve or place the donor at increased risk for endstage renal disease (ESRD).
- Prior treatment of malignancy does not increase the operative risk of nephrectomy. A prior history of malignancy usually excludes live kidney donation but may be acceptable if:
- The specific cancer is curable and the potential transmission of the cancer can reasonably be excluded. Examples include: colon cancer (Dukes A, >5 years ago), nonmelanoma skin cancer, or carcinoma in situ of the cervix.

**Drug Use**

Cessation of alcohol abuse defined by DSM-3: 60 g alcohol/ day sustained >6 months should be avoided for a minimum of 4 weeks to decrease the known risk of postoperative morbidity.
UNOS (2013)
Prospective Crossmatching. A prospective crossmatch is mandatory for all potential living donor recipients. *(Source of recommendation unclear.)*

ERBP (2013)
- We suggest that at least one typing is performed by molecular HLA typing of patients and donors to avoid mistakes in the classification of the HLA antigens. *(2D)*
- We suggest that HLA typing is performed in duplicate, preferentially on separate samples obtained at different occasions to avoid logistical errors. *(Ungraded Statement)*
- In case of sensitized patients, we recommend additional serological typing of the donor cells to be used for crossmatches in order to check the proper expression of the HLA antigens on the target cells. *(1D)*
- For highly sensitized patients with allele-specific antibodies we suggest to consider high-resolution molecular typing in both recipients and donors. *(2D)*

British Transplantation Society (2011)
- Initial assessment of donor and recipient histocompatibility status should be undertaken at an early stage in living donor kidney transplant workup to avoid unnecessary and invasive clinical investigations. *(B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)*
- Screening of potential living donor kidney transplant recipients for clinically relevant antibodies is important for ensuring optimal donor selection and graft survival. *(A1: Recommendation made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)*
- Antibody screening is especially important when potential living donor recipients reduce or withdraw immunosuppression. *(B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)*
- Post-transplant antibody monitoring should be undertaken according to the BSHI/BTS guidelines. *(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)*
- Transplant units and histocompatibility laboratories should agree an evidence-based protocol to define crossmatch results which constitute a veto to transplantation. *(B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)*
- A pre-transplant serum sample collected within 14 days of the planned date for transplantation must be tested in a sensitive crossmatch and if the crossmatch test is positive transplantation should not usually be performed, unless the antibody is shown to be indicative of acceptable immunological risk. *(A1: Recommendation made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)*
- Changes in immunosuppression during the transplant work-up should be notified to the histocompatibility laboratory and additional antibody screening and donor-recipient crossmatch tests undertaken as required. *(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)*
- HLA matching should be considered of benefit when there is an option of selecting between living
donors, particularly in reducing the possibility of subsequent sensitisation. This is important for younger recipients where repeat transplantation may be required. However, it is recognised that other donor factors will be taken into. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

- The histocompatibility laboratory should issue an interpretive report stating the donor and recipient HLA mismatch, recipient sensitisation status and crossmatch results, and define the associated immunological risk for all living donor-recipient pairs. (A1: Recommendation made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)

**SEN ONT (2010)**

SEN-ONT places - HLA typing. First crossmatch-immunological study of the recipient, in the first of three steps of the Donor Study.
28. Known psychological outcomes/benefits to donor

UNOS (2013)
Potential psychosocial risks:
- Problems with body image;
- Post-surgery depression or anxiety;
- Feelings of emotional distress or bereavement if the transplant recipient experiences any recurrent disease or in the event of the transplant recipient’s death; and
- Impact of donation on the donor’s lifestyle.

The psychosocial evaluation must be performed by a psychiatrist, psychologist, and/or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the donor record. The psychosocial evaluation must include the following components:

- Assess for any psychosocial (including mental health) issues that might complicate the living donor’s recovery and identify potential risks for poor psychosocial outcome;
- Assess for the presence of high-risk behaviors as defined by the US Public Health Service (PHS) that have the potential to increase the risk of disease transmission to the recipient;
- Assess history of smoking, alcohol, and drug use/abuse and dependency;
- Identify factors that warrant educational or therapeutic intervention prior to final donation decision;
- Determine that the potential donor understands the short and long-term medical and psychosocial risks associated with living donation, for both donor and recipient;
- Assess whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reason(s) for volunteering to donate and the nature of the relationship (if any) to the transplant candidate;
- Assess the potential donor’s ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes the potential donor having a realistic plan for donation and recovery, with social, emotional and financial support available as recommended; and
- Review the occupation, employment status, health insurance status, living arrangements, and social support of the potential donor and determine if the potential donor understands the potential financial implications of living donation. (Source of recommendation unclear.)

British Transplantation Society (2011)
Authors recommend that all health professionals involved in living donor kidney transplantation acknowledge the wide range of complex moral issues which are associated with this area of transplantation and ensure that good ethical practice consistently underpins clinical practice to achieve optimum outcomes. (Recommendation not graded, based on Expert Opinion.)

Support for the prospective donor, recipient and family is an integral part of the donation/transplantation process. Psychological needs must be identified at an early stage in the evaluation to ensure that appropriate support and/or intervention is initiated. Access to specialist psychiatric/psychological services must be available for donors/recipients requiring referral. (B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)

CARI (2010)
• A formal psychosocial assessment should be a mandatory part of the pre-transplant workup process.
• Semi-structured interview guides (for preoperative and postoperative psychosocial assessments) are useful for focusing the discussion on relevant and critical issues while allowing open discussion.
• Education and assessment of potential donors is essential to identify ‘high-risk’ donors.
• Donors should be followed-up for psychological care post-donation.
• Donors with poor recipient outcomes should have extensive psychological support available.
• A formal multidisciplinary approach should be taken in the event of negative recipient outcome.

(Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

WHAT DO THE OTHER GUIDELINES SAY? [CARI lists other guidelines]

Kidney Disease Outcomes Quality Initiative: No recommendation.

UK Renal Association: The doctor looking after the donor has a responsibility to inform donors of psychosocial issues around transplantation.

Canadian Society of Nephrology: No recommendation.

European Best Practice Guidelines: No recommendation.

Organ Procurement and Transplantation Network (OPTN):
The program has a responsibility to have available to the potential donor a donor team that consists of at least the following: physician/surgeon, transplant coordinator/nurse clinician, medical social worker, psychiatrist or psychologist, ethicist/clergy.

The donor team’s function is to:
1. Educate the potential donor regarding the potential risks and benefits
2. Provide counselling and support regarding family, disability, intellectual, emotional or other pressures
3. Determine that the donor’s decision is voluntary, without coercion
4. Provide opportunities for the donor to ‘opt out’ of the procedure without consequences.

Psychiatric and social screening: the dedicated mental health professional familiar with transplantation and living donation should evaluate the potential donor for:
1. Psychosocial history
2. Relationship between the donor and recipient and potential areas where undue pressure or coercion may be applied
3. Presence of psychiatric disorder
4. Existence of a financial incentive as motivation
5. Presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

The Canadian Council for Donation and Transplantation:
Pre-donation psychosocial evaluation should be conducted by a clinical social worker (with the appropriate knowledge and skill set) who is independent of the intended recipient’s care team. A psychosocial evaluation should be based on a semi-structured tool. This tool should guide discussion while enabling the latitude necessary for individual variation. The timing of the psychosocial evaluation should be left to the discretion of the living donor coordinator on the basis of the initial interview. Suggested components of the evaluation include:

• An exploration of the motivation for organ donation (how the decision was made, evidence of coercion or inducement, expectations and ambivalence)
• The nature of the relationship between donor and recipient (strengths, past conflicts/difficulties)
• Attitudes of significant others towards donation (availability of emotional and practical assistance)
• Knowledge and comprehension about the surgery and recovery
• Review of work- or school-related issues
• Mental health history and current status (psychiatric disorders, substance abuse, cognitive ability, competence, and capacity)
• Psychosocial history and current status (marital stress, living arrangements, religious beliefs and orientation, concurrent stressors, coping strategies).

**British Transplantation Society (2011)**
- All health professionals involved in living donor kidney transplantation must acknowledge the wide range of complex moral issues which are associated with this area of transplantation and ensure that good ethical practice consistently underpins clinical practice to achieve optimum outcomes. The BTS has an Ethics Committee to provide additional support and advice if required (Not graded)
- Support for the prospective donor, recipient and family is an integral part of the donation/transplantation process. Psychological needs must be identified at an early stage in the evaluation to ensure that appropriate support and/or intervention is initiated. Access to specialist psychiatric/psychological services must be available for donors/recipients requiring referral. *(B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)*

**SEN ONT (2010)**
Donors must visit a psychiatrist or a clinical psychologist if there is a chance that they suffer from any mental disorders or intellectual deficiencies. Although, a psychiatric diagnosis does not necessarily rule out donation. Hospitals vary greatly in this respect, but the systematic study of psychosocial aspects in all donor-recipient pairs by a psychiatrist or clinical psychologist and a social worker with experience in LDKT is very important.

**EAU (2009)**
It is advisable to obtain a psychiatric or independent medical evaluation of the donor's motivation, fitness and his ability to understand the risks of the operation. *(Grade recommendation: B, Based on well-conducted clinical studies, but without randomised clinical trials.)*
29. Known financial costs and insurability implications of donation.

UNOS (2013)
- The organ recipient’s transplant center is responsible for transportation costs for living donor kidney(s) and associated tissue typing material pursuant to CMS regulations.
- The organ recipient’s transplant center is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a living donor kidney. The organ recipient transplant center that requested the tissue typing material is responsible for the payment of transportation costs for the tissue typing material sent to crossmatch potential recipients for a non-renal organ. (Source of recommendation unclear.)

UNOS identifies the following potential financial impacts:
- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs;
- Need for life-long follow-up at the donor’s expense;
- Loss of employment or income;
- Negative impact on the ability to obtain future employment;
- Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance; and,
- Future health problems experienced by living donors following donation may not be covered by the recipient’s insurance.

British Transplantation Society (2011)
- The reimbursement of legitimate expenses incurred by a living donor as a direct result of the preparation for an act of donation is supported by the Department of Health. Prospective agreement for reimbursement from local recipient commissioners is currently recommended as the most effective mechanism for achieving reimbursement but a national scheme is being developed which will replace this guidance in the near future and this guidance will be updated accordingly. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)
- Donors from overseas present unique logistical challenges. In order for the process to be clinically effective and to comply with UK Border Agency and Department of Health requirements, there is an agreed entry clearance (visa) application process and duration of stay in the UK (6 months) for the donor which must be honoured in all but exceptional, unforeseen circumstances. (B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)

CST(2011)
We recommend that potential living organ donors be reimbursed for out-of-pocket expenses independent of the decision to proceed with donation. Such expenses should be reimbursed within pre-defined limits for specific expenses. Types of expenses include travel (e.g., mileage, economy airfare, care rental, and parking), accommodations and meal, incidental medical expenses not covered by health insurance, child- or elder-care, domestic health and certain long distance telephone charges. We recommend that reimbursement be equitable across jurisdiction and among donors.
We recommend reasonable and fair reimbursement of lost income for living organ donors. We recommend that access to remuneration be equitable across jurisdictions and among donors. (Recommendations based on Expert Opinion and Existing Guidelines.)

**SEN ONT (2010)**
No recommendations identified (Search terms included: financial, costs, insurability).

**EAU (2009)**
- Legislation in every European country forbids payment for organs. (Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)
- There should be a national insurance plan that provides life and disability insurance for all living donors. (Grade recommendation: B, Based on well-conducted clinical studies, but without randomised clinical trials.)

**Declaration of Istanbul (2008)**
Comprehensive reimbursement of the actual, documented costs of donating an organ does not constitute a payment for an organ but is rather part of the legitimate costs of treating the recipient.

a. Such cost-reimbursement would usually be made by the party responsible for the costs of treating the transplant recipient (such as a government health department or a health insurer);

b. Relevant costs and expenses should be calculated and administered using transparent methodology, consistent with national norms;

c. Reimbursement of approved costs should be made directly to the party supplying the service (such as to the hospital that provided the donor's medical care);

d. Reimbursement of the donor's lost income and out-of-pocket expenses should be administered by the agency handling the transplant rather than paid directly from the recipient to the donor.

Legitimate expenses that may be reimbursed when documented include:

a. the cost of any medical and psychologic evaluations of potential living donors who are excluded from donation (e.g., because of medical or immunologic issues discovered during the evaluation process);

b. costs incurred in arranging and effecting the preoperative, perioperative, and postoperative phases of the donation process (e.g., long-distance telephone calls, travel, accommodation, and subsistence expenses);

b. medical expenses incurred for post discharge care of the donor;

d. lost income in relation to donation (consistent with national norms). (Recommendation is derived from an international experience of participants and also from evidence-based recommendations.)

**NHMRC (2007)**
It may be ethically acceptable for people to be reimbursed for financial costs associated with being a living donor, but such reimbursement should aim to remove financial barriers to donation rather than act as an incentive to encourage people to donate organs or tissues.
NKF/AST (2000)

Authors list the following as “Elements of Disclosure for Potential Living Donors”:

- Potential impact of donation on the ability of the donor to obtain health and life insurance.  
  (Source of recommendation unclear.)
This psychosocial evaluation must be performed by a psychiatrist, psychologist, and/or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the donor record. The psychosocial evaluation must include the following components:

- Assess for any psychosocial (including mental health) issues that might complicate the living donor’s recovery and identify potential risks for poor psychosocial outcome;
- Assess for the presence of high-risk behaviors as defined by the US Public Health Service (PHS) that have the potential to increase the risk of disease transmission to the recipient;
- Assess history of smoking, alcohol, and drug use/abuse and dependency;
- Identify factors that warrant educational or therapeutic intervention prior to final donation decision;
- Determine that the potential donor understands the short and long-term medical and psychosocial risks associated with living donation, for both donor and recipient;
- Assess whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reason(s) for volunteering to donate and the nature of the relationship (if any) to the transplant candidate;
- Assess the potential donor’s ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes the potential donor having a realistic plan for donation and recovery, with social, emotional and financial support available as recommended; and
- Review the occupation, employment status, health insurance status, living arrangements, and social support of the potential donor and determine if the potential donor understands the potential financial implications of living donation. (Source of recommendation unclear.)

British Transplantation Society (2011)
Access to specialist psychiatric/psychological services must be available for donors/recipients requiring referral (B2)

CARI (2010)
Recommendation does not specify who should perform the evaluation. (Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

SEN ONT (2010)
Donors must visit a psychiatrist or a clinical psychologist if there is a chance that they suffer from any mental disorders or intellectual deficiencies.
EAU (2009)
Authors indicate that a psychiatric or independent medical evaluation of a potential donor be obtained, but do not recommend who should perform the evaluation. (Source of recommendation unclear.)

Declaration of Istanbul (2008)
All donors should undergo psychosocial evaluation by mental health professionals during screening. (Recommendation is derived from an international experience of participants and also from evidence-based recommendations.)

NHMRC (2007)
We recommend that the pre-donation psychosocial evaluation be conducted by a clinical social worker (with appropriate knowledge and skill set) who is independent of the intended recipient’s care team.

We recommend that a psychosocial evaluation be based on a semi-structured tool. This tool should guide discussion while enabling the latitude necessary for individual variation.

We recommend that the timing of the psychosocial evaluation be left to the discretion of the living donor coordinator on the basis of the initial review.

Because of the sensitive issues involved and the need for a comprehensive psychological assessment, this part of the evaluation should be carried out by a health professional who: a) has appropriate training and experience in mental health (e.g. psychiatrist, psychologist, clinical social worker); b) is experienced in the psychology of transplantation; and c) may be a member of the medical team responsible for donor evaluations or an external consultant to the team.

Core components of pre-donation psychological assessment of living donors:
a) reasons for donation;
b) relationship between donor and recipient;
c) attitudes of significant others toward the donation;
d) psychological health history and current status; and
e) education about mental health outcomes following donation.

UNOS/ASTS (2007)
The unrelated donor’s psychosocial evaluation should be

- guided by the following primary goals: To identify and appraise any potential psychosocial risks for a poor psychosocial outcome, including risks related to the individual’s psychiatric history or social stability.
- To ensure that the prospective donor comprehends the risks, benefits and potential outcome of the donation for herself or himself and the recipient, and that the donor understands that data on long-term donor psychosocial outcomes continue to be sparse.
- To assess the donor’s capacity to make the decision to donate and ability to cope with major surgery and related stresses.
• To assess donor motives and the degree to which the donation decision is made free of guilt, undue pressure, enticements or impulsive responses.
• To review lifestyle circumstances (e.g. employment, family relationships) that might be affected by donation.
• To determine that support systems are in place and ensure a realistic plan for donation and recovery, with adequate social, emotional and financial support and resources.
• To identify any factors that warrant educational or therapeutic intervention before donation can be undertaken. *(Recommendation is based on Expert Opinion.)*

Required components of the psychosocial evaluation of living unrelated kidney donors

**History and current status:** Obtain standard background information regarding such areas as the prospective donor’s educational level, living situation, cultural background, religious beliefs and practices, significant relationships, family psychosocial history, employment, lifestyle, community activities, legal offense history and citizenship.

**Capacity:** Ensure that the prospective donor’s cognitive status and capacity to comprehend information are not compromised and do not interfere with judgment; determine risk for exploitation.

**Psychological status:** Establish the presence or absence of current and prior psychiatric disorder, including but not limited to mood, anxiety, substance use and personality disorders. Review current or prior therapeutic interventions (counseling, medications), physical, psychological or sexual abuse, current stressors (e.g. relationships, home, work), recent losses, chronic pain management. Assess repertoire of coping skills to manage previous life or health-related stressors.

**Relationship with the transplant candidate:** Review the nature and degree of closeness (if any) to the recipient, e.g. how the relationship developed; and whether the transplant would impose expectations or perceived obligations on the part of either the donor or the recipient.

**Motivation:** Explore the rationale and reasoning for volunteering to donate, i.e. the ‘voluntariness’, including whether donation would be consistent with past behaviors, apparent values, beliefs, moral obligations or lifestyle, and whether it would be free of coercion, inducements, ambivalence, impulsivity or ulterior motives (e.g. to atone or gain approval, to stabilize self-image, to remedy psychological malady).

**Donor knowledge, understanding and preparation:** Explore the prospective donor’s awareness of any potential short- and long-term risks for surgical complications and health outcomes, both for the donor and the transplant candidate; recovery and recuperation time; availability of alternative treatments for the transplant candidate; financial ramifications (including possible insurance risk). Determine that the donor understands that data on long-term donor health and psychosocial outcomes continue to be sparse. Assess the prospective donor’s understanding, acceptance and respect for the specific donor protocol, e.g. willingness to accept potential lack of communication from the recipient; willingness to undergo future donor follow-up.

**Social support:** Evaluate significant other, familial, social and employer support networks available to the prospective donor on an ongoing basis as well as during the donor’s recovery from surgery.

**Financial suitability:** Determine whether the prospective donor is financially stable and free of financial hardship; has resources available to cover financial obligations for expected and unexpected donation-related expenses; is able to withstand time away from work or established role, including unplanned extended recovery time; has disability and health insurance. The Transplantation Society & International Society of Nephrology (Istanbul, 2008)

**AST (2001)**

While authors did not recommend who should provide the evaluation, they do recommend that psychiatric clearance is necessary for the non-directed living donor to protect their well-being.
(Recommendations based on consensus opinions. Synthesized by authors after extensive literature review.)


The psychosocial evaluation should be performed by a trained mental health professional (i.e., clinical social worker, psychologist, psychiatrist or psychiatric nurse) experienced in transplantation. The psychosocial evaluation should be a professional not involved in the care of the recipient.

A psychosocial evaluation is necessary for each potential donor. The goals of such an evaluation are 3-fold: to evaluate psychological, emotional and social stability to rule out unsuitable donors and enhance the donation process by identifying individual or donor-related factors that warrant appropriate intervention; to establish whether the potential donor is competent to give informed consent; and to assess the degree to which the decision to donate is being made freely, without undue pressure or coercion. *(Source of recommendation unclear.)*
Due to the increasing problems associated with organ trade, transplant tourism and organ donor trafficking, The Transplantation Society (TTS) and the International Society of Nephrology (ISN) recently issued the Istanbul Declaration. The Declaration urges countries to legislate and prohibit unethical practices, provide healthcare to citizens that have been victims of organ trafficking, improve controls to protect their people from exploitation and to develop procedures that allow national self-sufficiency in organ donation. Furthermore, they recommend dissolving scientific societies that accept members who do not adhere to the declaration. They also recommend that industry should not collaborate with these professionals or finance their initiatives, and that scientific journals should not accept their publications.

Declaration of Istanbul (2008)

Organs for transplantation should be equitably allocated within countries or jurisdictions to suitable recipients without regard to gender, ethnicity, religion, or social or financial status.

a. Financial considerations or material gain of any party must not influence the application of relevant allocation rules.

Jurisdictions, countries, and regions should strive to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents in need from within the country or through regional cooperation.

a. Collaboration between countries is not inconsistent with national self-sufficiency as long as the collaboration protects the vulnerable, promotes equality between donor and recipient populations, and does not violate these principles;

b. Treatment of patients from outside the country or jurisdiction is only acceptable if it does not undermine a country’s ability to provide transplant services for its own population.

Organ trafficking and transplant tourism violate the principles of equity, justice, and respect for human dignity and should be prohibited. Because transplant commercialism targets impoverished and otherwise vulnerable donors, it leads inexorably to inequity and injustice and should be prohibited. In Resolution 44.25, the World Health Assembly called on countries to prevent the purchase and sale of human organs for transplantation.

a. Prohibitions on these practices should include a ban on all types of advertising (including electronic and print media), soliciting, or brokering for the purpose of transplant commercialism, organ trafficking, or transplant tourism.

b. Such prohibitions should also include penalties for acts, such as medically screening donors or organs, or transplanting organs, that aid, encourage, or use the products of, organ trafficking or transplant tourism. Practices that induce vulnerable individuals or groups (such as illiterate and impoverished persons, undocumented immigrants, prisoners, and political or economic refugees) to become living donors are incompatible with the aim of combating organ trafficking, transplant tourism, and transplant commercialism.

To respond to the need to increase deceased donation
1. Governments, in collaboration with healthcare institutions, professionals, and nongovernmental organizations should take appropriate actions to increase deceased organ donation. Measures should be taken to remove obstacles and disincentives to deceased organ donation.

2. In countries without established deceased organ donation or transplantation, national legislation should be enacted that would initiate deceased organ donation and create transplantation infrastructure, so as to fulfill each country's deceased donor potential.

3. In all countries in which deceased organ donation has been initiated, the therapeutic potential of deceased organ donation and transplantation should be maximized.

4. Countries with well-established deceased donor transplant programs are encouraged to share information, expertise, and technology with countries seeking to improve their organ donation efforts. (Recommendation is derived from an international experience of participants and also from evidence-based recommendations.)
We recommend that follow-up regarding the psychosocial impact of living donation be conducted after donation for every living donor during the first post-donation year. We recommend that either the living donor coordination or social worker associated with the living donor program (dependent on whoever has an established relationship) should ideally conduct the psychosocial assessment post-donation. We recommend that a semi-structured interview be used to assess the psychosocial impact of organ donation following surgery. (Recommendations based on Expert Opinion and Existing Guidelines.)

CARI (2010)
- Donors should be followed-up for psychological care post-donation.
- Donors with poor recipient outcomes should have extensive psychological support available.
- A formal multidisciplinary approach should be taken in the event of negative recipient outcome.
(Recommendation based on Expert Opinion and low level evidence. No recommendations possible based on Level I or Level II evidence.)

WHAT DO THE OTHER GUIDELINES SAY?
Kidney Disease Outcomes Quality Initiative: No recommendation.
UK Renal Association: The doctor looking after the donor has a responsibility to inform donors of psychosocial issues around transplantation.
Canadian Society of Nephrology: No recommendation.
European Best Practice Guidelines: No recommendation.
Organ Procurement and Transplantation Network (OPTN): The program has a responsibility to have available to the potential donor a donor team that consists of at least the following: physician/surgeon, transplant coordinator/nurse clinician, medical social worker, psychiatrist or psychologist, ethicist/clergy.
The donor team’s function is to: 1. Educate the potential donor regarding the potential risks and benefits 2. Provide counseling and support regarding family, disability, intellectual, emotional or other pressures 3. Determine that the donor’s decision is voluntary, without coercion 4. Provide opportunities for the donor to ‘opt out’ of the procedure without consequences. Psychiatric and social screening: the dedicated mental health professional familiar with transplantation and living donation should evaluate the potential donor for: 1. Psychosocial history 2. Relationship between the donor and recipient and potential areas where undue pressure or coercion may be applied 3. Presence of psychiatric disorder 4. Existence of a financial incentive as motivation 5. Presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.
The Canadian Council for Donation and Transplantation: Pre-donation psychosocial evaluation should be conducted by a clinical social worker (with the appropriate knowledge and skill set) who is independent of the intended recipient’s care team. A psychosocial evaluation should be based on a semi-structured tool. This tool should guide discussion while enabling the latitude necessary for individual variation. The timing of the psychosocial evaluation should be left to the discretion of the living donor coordinator on the basis of the initial interview. Suggested components of the evaluation include: • An exploration of the motivation for organ donation (how the decision was made, evidence of coercion or inducement, expectations and ambivalence)
• The nature of the relationship between donor and recipient (strengths, past conflicts/difficulties)
• Attitudes of significant others towards donation (availability of emotional and practical assistance)
• Knowledge and comprehension about the surgery and recovery
• Review of work- or school-related issues
• Mental health history and current status (psychiatric disorders, substance abuse, cognitive ability, competence, and capacity)
• Psychosocial history and current status (marital stress, living arrangements, religious beliefs and

**Declaration of Istanbul (2008)**

All donors should be offered psychosocial services as a standard component of follow-up. *(Recommendation is derived from an international experience of participants and also from evidence-based recommendations.)*
We recommend mandatory follow-up by a medical/surgical member between 4-12 weeks and at 12 months after donation for all donors. Depending on the scope of the procedure, additional follow-up may be required during the first post-donation year.

We recommend lifelong follow-up of organ donors.

We recommend that the donor be primarily responsible for ensuring that follow-up is completed beyond the first post-donation year, with coordination, education and health promotion by the donor assessment team and care provided by the family physician or the health care provider. (Recommendations based on Expert Opinion and Existing Guidelines.)

A scientific registry should be established, as well as a prospective regular data collection. This will allow for a better assessment of the long-term risk of uninephrectomy and an early detection of new medical data that would contribute to redefine current criteria for kidney donation and establish new requirements in donor evaluation protocols.

The health and well-being of living donors should be monitored in a follow-up register to document any long-term medical problems due to donation. (Grade of recommendation: B, Based on well-conducted clinical studies, but without randomised clinical trials.)

Ongoing care of donors
• Make arrangements for continuing medical and psychological follow-up of living donors
• If a donor is identified as unsuitable, be sensitive in communicating why this is so and make arrangements for appropriate care or referral.
• If communicating poor outcomes of transplantation to the donor be sensitive to the time, place and manner in which the information is given.

Donors should be offered medical and psychological care related to the donation process, for at least one year or until any complications have resolved. The health care professional who acted as an advocate for the donor through the donation process would be a valuable member of the team providing follow-up.

Conference participants recommended the development of a living donor registry that would collect demographic, clinical, and outcome information on all living organ donors. The rationale for this registry includes concern for donor well-being, limitations of current knowledge regarding the long-term consequences of donation, the potential to evaluate the impact of changes in criteria for donor eligibility on the outcome of donors and the need within the transplant community to develop mechanisms to provide for quality assurance assessments. (Source of recommendation unclear.)
UNOS (2013)
Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.

The goal of informed consent is to ensure that a potential donor understands:
1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
2) That there are both general risks of the operation as well as center specific risks.

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:
   a. Written assurance by the potential donor that he or she is willing to donate, free from inducement and coercion, and has been informed that he or she may decline to donate at any time. Potential donors must be offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential. The independent donor advocate (IDA) must be available to assist the potential donor during this process (see Policy 12.4)
   b. Instruction about all phases of the living donation process, which include consent, medical and psychosocial evaluations, pre- and post-operative care, and required post-operative follow-up (Policy 7.2) Teaching or instructional material can include any media (e.g., written, video, audio) or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the donor is able to engage in a meaningful dialogue with the transplant program staff.
   c. Disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.
   d. Disclosure that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations).
   e. Disclosure that the recovery hospital must provide an Independent Donor Advocate. (Source of recommendation unclear.)

ERBP (2013)
We recommend that the individual risk of donation should be carefully discussed with the donor, taking into account the situation of both donor and recipient. Ideally, this should be done using standardized check lists to ensure all items are discussed. (Ungraded Statement)

British Transplantation Society (2011)
It may on occasion be more difficult to establish that consent is both informed and freely given. For this reason, independence between the clinicians responsible for the donor and the recipient is recommended – allowing for, in effect, a donor advocate. A similar role may be played by a living donor coordinator, or more formally by an independent third party, the Independent Assessor. It is essential that this separation of responsibility remains standard and is applied to all potential living donors.

- The living donor must be offered the best possible environment for making a voluntary and informed choice about donation. In line with current best practice, relevant information about the recipient should be shared with the donor, provided that the recipient has given consent. The
recipient must be informed that lack of permission to disclosure under these circumstances may jeopardize the transplant proceeding (Not graded)

- Independent assessment of the donor and recipient is required by primary legislation (Human Tissue Act 2004). In order to achieve the best outcome for donor, recipient and transplant, the boundaries of confidentiality must be specified and discussed at the outset. Separate clinical teams for donor and recipient are considered best practice but healthcare professionals must work together to ensure effective communication and co-ordination of the transplant process without compromising the independence of either donor or recipient (Not graded)

- Support for the prospective donor, recipient and family is an integral part of the donation/transplantation process. Psychological needs must be identified at an early stage in the evaluation to ensure that appropriate support and/or intervention is initiated. Access to specialist psychiatric/psychological services must be available for donors/recipients requiring referral. (B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)

CST (2011)

We recommend that individuals consent to be evaluated as living donors before the assessment process proceeds beyond the initial stages of ABO blood grouping and the preliminary interview. For the purposes of this recommendation, consent consists of providing the information and confirming that it is comprehended by the potential donor.

We recommend that the following elements of disclosure be included in the informed consent process:

(a) Description of the assessment process, the surgical procedure, and the recuperative period.
(b) Process for handling unexpected findings (e.g., maternity/paternity, reporting of communicable diseases).
(c) Alternative donation procedures, even if only available at other transplant centers (e.g., in the case of kidney transplantation, laparoscopic vs. open nephrectomy).
(d) Potential complications for the donor:
   i. Surgical, including risk of death
   ii. Long-terms, including physical, psychosocial and financial
   iii. Impact of donation on the life-style, employment, and insurability of the donor
   iv. Impact of the discovery of an underlying condition on the ability of the individual to obtain health and life insurance.
(e) Resources available to the donor and any expenses to be borne by the donors (including potential hidden costs).
(f) Anticipated short- and long-term follow-up care.
(g) Outcomes for donors and recipients: transplant centre-specific and national.
(h) Information regarding material risks and benefits to potential recipients.
(i) Alternative treatments available to the recipient (other than living-donor transplant).
(j) The potential impact of isolated abnormalities (e.g., donor hypertension) identified during the donor assessment on the donor and recipient outcomes.
(k) In cases where incremental risk to either the donor or recipient is present, the information should be conveyed to both, subject to consent and a case by case balancing of rights to confidentiality.
(l) Information on possible unanticipated outcomes (e.g., non-use of the organ in the intended recipient or transmission of disease).
(m) Description of the withdrawal process, emphasizing the ability of the donor to withdraw at any time.
(n) Policies related to confidentiality of donor information (e.g., HLA typing, reason for withdrawal). *(Recommendations based on Expert Opinion and Existing Guidelines.)*

**SEN ONT (2010)**

Article 6 of the Law states certain requirements that must concur so that the doctor responsible for the transplant is able to give his or her approval for the intervention. The requirements must be considered with the recipient in mind, a patient whose rights are completely recognised by Law 41/2002:

a) The **recipient** is fully aware of the type of intervention that he or she is to undergo, and **fully understands the risks and expected benefits** associated with it.

b) The recipient has been **informed** that the relevant donor recipient compatibility tests have been conducted.

c) The **recipient expresses his or her consent** to perform the transplantation in writing. If the recipient is not of legal age (16 years old) or competent, consent would have to be given by a parent, tutor or guardian. This right to information is susceptible to being renounced, in the terms foreseen by the Spanish Law on Patient Independence.

**EAU (2009)**

The altruistic living donor must give informed consent, which can only be obtained if he or she has a proper understanding of the risk involved. *(Source of recommendation unclear.)*

**Declaration Istanbul (2008)**

Mechanisms for informed consent should incorporate provisions for evaluating the donor’s understanding, including assessment of the psychologic impact of the process.

**NHMRC (2007)**

**Understanding the situation**

- Be aware that decision-making in living donation can be highly charged and requires careful and sensitive handling, especially in situations where a potential donor’s main motive is to help a loved one.
- Consider the complexities of the relationships involved as these may affect the extent to which a decision whether or not to donate is genuinely voluntary.
- Ensure family and/or individual counselling is available to assist potential donors to come to a well-considered decision.

**Supporting informed decision-making**

- Provide information that is appropriate to the family’s understanding and experience, at a pace determined by their needs and the particular situation.
- Provide information in a sympathetic environment, using simple language, avoiding the use of clinical terms and allowing time for questions.
- Wherever possible, ensure sufficient time and care can be taken to allow informed decision-making.
- Involve Aboriginal Health Workers or Aboriginal Hospital Liaison Officers when communicating with Aboriginal and Torres Strait Islander people.
- Use culturally appropriate materials and the services of trained translators when providing information to people from culturally and linguistically diverse backgrounds.

**Making a decision on behalf of a child or dependent adult**
• Ensure the family understands that the decision-making process requires an independent assessment of the child or dependent person’s best interests in relation to donation.

Professional responsibility in decision-making
• Take all reasonable steps to establish that donation is altruistic and that no element of coercion or commerce is involved.
• Consider the balance of risks in each case and ensure that donation occurs within safe limits.
• In non-directed donation, ensure high levels of confidentiality for both donor and recipient.

Information provided to potential donors should include explanation of:
  a) the surgical procedure, recovery and recuperation, the risks of surgical complications and the potential for long-term medical complications;
  b) the potential for psychological effects both immediately after the donation and in the longer term (eg depression, guilt, relationship problems) and risk factors that make these more likely (eg past or current mental health conditions);
  c) possible changes to the donor/recipient relationship in directed donation (eg feelings of “ownership” towards the recipient by the donor or of intense gratitude by the recipient);
  d) the specific risks and benefits to the potential recipient, and the possibility of graft failure or death of the recipient;
  e) the availability of ongoing medical and psychological support for the donor;
  f) any other information that may affect the donor’s decision (eg potential bone marrow donors should be told that there may be a request for a second donation); and
  g) any uncertainty about the implications of donation on their ability to work and to obtain health and life insurance in the future.

UNOS/ASTS (2007)
1. The prospective living organ donor should be:
   a. capable of making the decision to donate.
   b. willing to donate.
   c. free of coercion, manipulation or undue solicitation by any party regarding the decision to donate.
   d. medically suitable to donate.
   e. psychosocially suitable to donate, based on an evaluation that includes a series of specific components
   f. fully informed of the risks and benefits to the donor, as demonstrated by the donor’s expression of understanding of these risks and benefits.
   g. fully informed of the risks, benefit and alternative treatment available to the recipient, within the constraints of the transplant center’s obligation to maintain confidentiality of recipient medical information.
   h. willing to sign a statement attesting that the donor is not providing the organ for monetary gain.
2. The prospective live organ donor should not be called upon to donate in clinically hopeless situations.
3. The benefits to both the donor and recipient should outweigh the risks associated with the donation and transplantation of the living donor organ.
4. Medical and psychosocial follow-up of the living organ donor after donation should be undertaken by the living donor program. (Recommendation is based on Expert Opinion.)

AST (2001)
General information about acute rejection, chronic rejection, and complications associated with both short- and long-term immunosuppression may be shared with both recipient and potential donor as
part of the formal consent process. (Recommendations based on consensus opinions. Synthesized by authors after extensive literature review.)


The person who gives consent to be a live organ donor should be competent, willing to donate and free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits and alternative treatments available to the recipient. Donors should not be called on to donate in clinically hopeless situations. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation of the living donor organ. (Source of recommendation unclear.)
37. Independent Donor Advocate

UNOS (2013)
The living kidney donor recovery hospital must provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.

The IDA must assist the potential living kidney donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process. IDA responsibilities include, but are not limited to the following:
- Promote the best interests of the potential living donor
- Advocate for the rights of the potential donor
- Assist the potential donor in obtaining and understanding information regarding the:
  - Consent process;
  - Evaluation process;
  - Surgical procedure;
  - Medical and psychosocial risks;
  - Benefit and need for follow-up. (Source of recommendation unclear.)

EBRP (2013)
We suggest that the donor be evaluated by an independent physician who is not part of the transplant team and is not involved in the daily care of the recipient, and when possible, by a psychologist. (Ungraded Statement)

British Transplantation Society (2011)
It may on occasion be more difficult to establish that consent is both informed and freely given. For this reason, independence between the clinicians responsible for the donor and the recipient is recommended – allowing for, in effect, a donor advocate. A similar role may be played by a living donor coordinator, or more formally by an independent third party, the Independent Assessor. It is essential that this separation of responsibility remains standard and is applied to all potential living donors.

CST (2011)
We recommend that an independent donor advocate be involved in the assessment of a potential living organ donor. Advocacy is a continuous process which may be shared among several professionals.

We recommend that the minimum attribute of an organ donor advocate is independence from the intended recipient’s care team.

In smaller programs, it may be difficult to identify health care professional with the specialized expertise required to conduct the donor assessment who are NOT involved in some aspect of the recipient care team. In this setting, we recommend that a physician who is not associated with either the donor or the recipient care teams (i.e., a general internist, an external specialist) act as an independent donor advocate. (Recommendations based on Expert Opinion and Existing Guidelines.)
NHMRC (2007)
Authors describe members of the multidisciplinary team involved in the organ donation process and include: Psychiatrist or psychologist — assesses whether the donor is psychologically healthy and whether donation poses any particular risks.

Each institution where living donation of organs or tissues by adults may be considered should have protocols in place to ensure that the donor has an independent advocate (who may or may not be involved in the assessments) who is involved in the final decision-making about donation.

AST (Steinman, 2001)
If the decision is made to evaluate a potential donor, then that individual must have their own physician who serves as their advocate. The nephrologist caring for the potential recipient should never evaluate the donor. This separation is mandatory to prevent a conflict of interest. Another nephrology member of the transplant team who has no direct involvement with the potential recipient can evaluate the potential donor. This relationship ensures donor advocacy and confidentiality, allowing the potential donor to properly express their thoughts about donation. (Recommendations based on consensus opinions. Synthesized by authors after extensive literature review.)
UNOS (2013)
Donor age <18 is a contraindication. *(Source of recommendation unclear.)*

EBRP (2013)
We recommend that old age in itself is not a contraindication to donation. *(1B)*

British Transplantation Society (2011)
- Old age alone is not an absolute contraindication to donation but the medical work-up of older donors must be particularly rigorous to ensure they are suitable. *(A1: Recommendation made base on high quality of evidence, Strength of recommendation evaluated at a “We recommend” level.)*
- Both donor and recipient should be made aware that the older donor may be at greater risk of peri-operative complications and that the function and possibly the long-term survival of the graft may be compromised. This is particularly evident with donors >60 years of age. *(B1 – Quality of Evidence has been graded as Moderate, “We recommend” is the strength of the recommendation.)*
- Children (age <18) should only be considered as living organ donors in exceptionally rare circumstances.
- A full psychological or psychiatric assessment should be sought if there is concern about the suitability of a donor on mental health grounds; for example, if there is evidence of previous or current mental illness, active substance abuse, dependence on prescribed medication, self-harming behaviour, or significantly dysfunctional family relationships, particularly between recipient and donor. Such an assessment is valuable in establishing when it is unsuitable to proceed to donation on these grounds.

CST (2011)
We strongly recommend that live organ donation from minors (<18 years) not be performed, In highly exceptional circumstance where such a donor may be considered, the evaluation and informed consent process should be altered to include the following requirements:
- An independent donor advocate: this person cannot be associated with either the donor or recipient care teams or the donor/recipient family.
- A consultation with the local ethics program.
- A psychosocial evaluation: conducted by an independent psychologist/psychiatrist experienced in adolescent medicine.
- Legal counsel. *(Recommendations based on Expert Opinion and Existing Guidelines.)*

SEN ONT (2010)
- The *minimum age for donation is 18 years in Spain*. It is particularly important to assess if very young donors are mature enough to make their own decisions.
- There is no set maximum age limit (although donation is rarely considered in patients over 70 years old in Spain).
- Organs must not be removed from donors that have not reached legal age, even when parents or tutors have provided consent.
- Living-donor organs must not be removed (or where applicable) used in cases where it could be suspected that consent has been given for financial gain or there is social or psychological coercion.

**EAU (2009)**

Donor age <18 is an absolute contraindication. *(Source of recommendation unclear.)*

**NHMRC (2007)**

**Making a decision on behalf of a child or dependent adult**

- Ensure the family understands that the decision-making process requires an independent assessment of the child or dependent person’s best interests in relation to donation.

Every child has the right to bodily integrity irrespective of the needs of others. A living child’s body or body parts should never be seen as a resource for another person.

**Amsterdam Forum (2005)**

Forum participants agreed that minors less than 18 years of age should not be used as living kidney donors. *(Recommendation based on Evidence-Based, Expert Opinion.)*


Conference participants created a list of Conditions in Which a Minor May Ethically Act as a Live Organ Donor. Those Conditions include:

- When the potential donor and recipient are both highly likely to benefit (as in the case of identical twins).
- When the surgical risk for the donor is extremely low.
- When all other opportunities for transplantation have been exhausted, no potential adult living donor is available and timely and/or effective transplantation from a cadaver donor is unlikely.
- When the minor freely agrees to donate without coercion (established by the independent donor advocate). *(Source of recommendation unclear.)*
41. What local laws and practices might influence donation decisions?

**British Transplantation Society (2011)**
- All kidney transplants performed from living donors must comply with the requirements of the primary legislation (Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006) which regulate transplantation and organ donation across the countries of the United Kingdom. (Not graded)
- Consent for the removal of organs from living donors, for the purposes of transplantation, must comply with the requirements of both the Human Tissue Act 2004, the common law for those under 16 years of age, and the Mental Capacity Act 2005 in England and Wales. Consent in Scotland must comply with the Human Tissue (Scotland) Act 2006 and the Adults with Incapacity (Scotland) Act 2000.

**EAU (2009)**
- In all countries without presumed consent law, efforts should be increased to recruit donors through an opting-in register or by carrying donor cards. *(Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)*
- Professional organisations within countries should, where necessary, put pressure on government health departments to maintain enough intensive care beds, create a cadre of national transplant co-ordinators and fund and deploy educational programmes for intensive care physicians. *(Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)*
42. Should some local laws be changed?

**EAU (2009)**
- In all countries without presumed consent law, efforts should be increased to recruit donors through an opting-in register or by carrying donor cards. *(Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)*
- Professional organisations within countries should, where necessary, put pressure on government health departments to maintain enough intensive care beds, create a cadre of national transplant co-ordinators and fund and deploy educational programmes for intensive care physicians. *(Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)*

**Declaration of Istanbul (2008)**
Legislation should be developed and implemented by each country or jurisdiction to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards.
- Policies and procedures should be developed and implemented to maximize the number of organs available for transplantation, consistent with these principles;
- The practice of donation and transplantation requires oversight and accountability by health authorities in each country to ensure transparency and safety;
- Oversight requires a national or regional registry to record deceased and living donor transplants;
- Key components of effective programs include public education and awareness, health professional education and training, and defined responsibilities and accountabilities for all stakeholders in the national organ donation and transplant system. *(Recommendation is derived from an international experience of participants and also from evidence-based recommendations.)*
43. What is minimum legislation needed to regulate donation.

CST (2011)
We recommend that transplant data be shared at the national level to best enhance live organ donation and transplantation. Such a strategy should be cost effective and sustainable, privacy compliant and responsive to change, resulting in information provided to transplant centers that improves the health and health care of organ donors and recipients. We recommend that a national longitudinal data base be developed to track medical outcomes of living donors. The following data are required:

(a) Baseline donor information (e.g., age, gender, relationship, relevant rest results)
(b) Donor identifiers to permit linking data with administrative databases
(c) Reporting of serious peri-operative complications (e.g., death, re-operation rate, re-admissions)
(d) Reporting of organ failure occurring in a living donor
(e) Reporting of a donor death in the year after surgery from any cause, or subsequent deaths believed to be related to the donation process.

Consideration may be given to:

(f) Data collection up to and including one year of follow-up
(g) Annual data collection beyond one year of follow-up (Recommendations based on Expert Opinion and Existing Guidelines.)

EAU (2009)

- There should be a national insurance plan that provides life and disability insurance for all living donors. (Grade of recommendation: B, Based on well-conducted clinical studies, but without randomised clinical trials.)
- In all countries without presumed consent law, efforts should be increased to recruit donors through an opting-in register or by carrying donor cards. (Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)
- Professional organisations within countries should, where necessary, put pressure on government health departments to maintain enough intensive care beds, create a cadre of national transplant co-ordinators and fund and deploy educational programmes for intensive care physicians. (Grade of recommendation: C, Made despite the absence of directly applicable clinical studies of good quality.)
### 44. Informed consent inclusions: Donor peri-operative complications.

#### UNOS (2013)
- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. *(Source of recommendation unclear.)*

#### NKF/AST (2000)
Authors list the following as “Elements of Disclosure for Potential Living Donors”:
- Description of the evaluation, the surgical procedure and the recuperative period
- Anticipated short and long-term follow-up care
- Alternative donation procedures, even if only available at other transplant centers
- Potential surgical complications for the donor, citing the reports of donor deaths (even if never experienced at that transplant center)
- Medical uncertainties, including the potential for long-term complications
- Any expense borne by the donor. *(Source of recommendation unclear.)*
45. Informed consent inclusions: Donor end-stage renal disease, need for RRT, AKI.

UNOS (2013)

- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. (Source of recommendation unclear.)

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following...

Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

a. On average, donors will have a 25-35% permanent loss of kidney function at donation.

b. Baseline risk of ESRD does not exceed that of members of the general population with the same demographic profile.

c. Donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occur, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD.

d. Donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be more rapid with only one kidney.

e. Dialysis is required when reaching ESRD.

f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates. (Policy 12.9.3)

NKF/AST (2000)

Authors list the following as “Elements of Disclosure for Potential Living Donors”:

- Medical uncertainties including the potential for long-term donor complications. (Source of recommendation unclear.)

**UNOS (2013)**
- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks.

(Source of recommendation unclear.)

Authors list the following as “Elements of Disclosure for Potential Living Donors”:
- Potential surgical complications for the donor, citing the reports of donor deaths (even if never experienced at that transplant center). (Source of recommendation unclear.)
47. Informed consent inclusions: Donor CVD events.

UNOS (2013)
- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. (Source of recommendation unclear.)

NKF/AST (2000)
Authors list the following as “Elements of Disclosure for Potential Living Donors”:
- Medical uncertainties including the potential for long-term donor complications. (Source of recommendation unclear.)
UNOS (2013)

- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. *(Source of recommendation unclear.)*

NKF/AST (2000)

Authors list the following as “Elements of Disclosure for Potential Living Donors”:

- Medical uncertainties including the potential for long-term donor complications. *(Source of recommendation unclear.)*
UNOS (2013)
- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. (Source of recommendation unclear.)

NKF/AST (2000)
Authors list the following as “Elements of Disclosure for Potential Living Donors”:
- Medical uncertainties including the potential for long-term donor complications. (Source of recommendation unclear.)
UNOS (2013)

- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. *(Source of recommendation unclear.)*

NKF/AST (2000)

Authors list the following as “Elements of Disclosure for Potential Living Donors”:
- Medical uncertainties including the potential for long-term donor complication. *(Source of recommendation unclear.)*
UNOS (2013)

- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. *(Source of recommendation unclear.)*

NKF/AST (2000)

Authors list the following as "Elements of Disclosure for Potential Living Donors":

- Medical uncertainties including the potential for long-term donor complications. *(Source of recommendation unclear.)*
UNOS (2013)

- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. (Source of recommendation unclear.)

NKF/AST (2000)

Authors list the following as “Elements of Disclosure for Potential Living Donors”:
- Information regarding specific risks and benefits to the potential recipient. (Source of recommendation unclear.)
53. Informed consent inclusions: Recipient graft survival (with respect to donor characteristics such as age, obesity, BP, kidney function, etc.)

UNOS (2013)

- Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.
- The goal of informed consent is to ensure that a potential donor understands:
  1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
  2) That there are both general risks of the operation as well as center specific risks. (Source of recommendation unclear.)

Living Kidney Donor Consent

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:

a. Written assurance by the potential donor that he or she is willing to donate, free from inducement and coercion, and has been informed that he or she may decline to donate at any time. Potential donors must be offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential. The independent donor advocate (IDA) must be available to assist the potential donor during this process. (see Policy 12.4)

b. Instruction about all phases of the living donation process, which include consent, medical and psychosocial evaluations, pre- and post-operative care, and required post-operative follow-up. (Policy 7.2) Teaching or instructional material can include any media (e.g., written, video, audio) or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the donor is able to engage in a meaningful dialogue with the transplant program staff.

c. Disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

d. Disclosure that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations).

e. Disclosure that the recovery hospitals must provide an Independent Donor Advocate (IDA).

British Transplantation Society (2011)

- The living donor must be offered the best possible environment for making a voluntary and informed choice about donation. In line with current best practice, relevant information about the recipient should be shared with the donor, provided that the recipient has given consent. The recipient must be informed that lack of permission to disclosure under these circumstances may jeopardise the transplant proceeding. (Not graded)

- Independent assessment of the donor and recipient is required by primary legislation (Human Tissue Act 2004). In order to achieve the best outcome for donor, recipient and transplant, the boundaries of confidentiality must be specified and discussed at the outset. Separate clinical teams for donor and recipient are considered best practice but healthcare professionals must work together to ensure effective communication and co-ordination of the transplant process without compromising the independence of either donor or recipient. (Not graded)
Support for the prospective donor, recipient and family is an integral part of the donation/transplantation process. Psychological needs must be identified at an early stage in the evaluation to ensure that appropriate support and/or intervention is initiated. Access to specialist psychiatric/psychological services must be available for donors/recipients requiring referral. (B2: Moderate quality of evidence, associated with a “we suggest” strength of recommendation.)

SENT ONT (2010)

- The document should be written with simple words and short phrases, should avoid numerical expressions indicating probability, and should be no longer than two pages. It should at least include a brief description of the procedure, the intervention’s risks and those related to the donor’s personal circumstances, the important health consequences and a section for statements and signatures where any specific conditions and revocation clauses may be included.
- All potential donors should be able to show that they understand the information provided, the risks and benefits that are involved with the donation, the benefits and alternative treatments available to the recipient and the actual medium- and long-term consequences.