The KPD Protocol
Assessment of Living Donors in Canada

Dr. Bob Richardson
Head, Living Donor Assessment Group, UHN
Member, Living Donor Advisory Committee to Canadian Blood Services
Plan

- The KPD protocol is a document defining standardized assessment and acceptance criteria for Living Donors across Canada
- Why a Protocol for assessment and acceptance of living donors was necessary
- A brief description of the testing and acceptance criteria for living donors
- What nephrology health care providers need to know about living donors
Objectives

- Understand how the KPD protocol supports the KPD program in Canada
- Understand the methodology used by the LDAC to create the new Canadian standards
- Know the highlights of the standards
The Background: Canadian Blood Services

- Manages blood donation system
- OneMatch Stem Cell and Marrow Network
- Umbilical cord blood bank
- **Leading national practices, professional education, public awareness and system performance activities for organ and tissue donation and transplantation**
- Managing national patient registries for organ donation and transplantation
- Bulk purchasing of pharmaceutical plasma protein products
- Providing diagnostic laboratory testing services in some provinces
- Conducting leading-edge research and advancing practice in transfusion and transplantation medicine nationally and internationally
Living Donor Advisory Committee

- First meeting January 2012
- To promote living donation in Canada

**Participating Members:**

<table>
<thead>
<tr>
<th>David Landsberg (Chair)</th>
<th>Olwyn Johnston</th>
<th>Christine Pippy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maureen Connelly</td>
<td>Dale Lien</td>
<td>Robert Richardson</td>
</tr>
<tr>
<td>Christine Dipchand</td>
<td>Ruth McCarrell</td>
<td>Leroy Storsley</td>
</tr>
<tr>
<td>Amit Garg</td>
<td>Rahul Mainra</td>
<td>Linda Wright</td>
</tr>
<tr>
<td>David Grant</td>
<td>Thomas Mueller</td>
<td>Serdar Yilmaz</td>
</tr>
<tr>
<td>Isabelle Houde</td>
<td>Peter Nickerson</td>
<td>Kimberly Young</td>
</tr>
</tbody>
</table>

**Canadian Blood Services:**

<table>
<thead>
<tr>
<th>Tracy Brand</th>
<th>Dena Rice</th>
<th>PJ Vankoughnett-Olson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debra Cadelli</td>
<td>Bryan Sandilands</td>
<td>Kathy Yetzer</td>
</tr>
</tbody>
</table>
First Assignment

- Harmonize testing and acceptance protocols across Canadian living donor programs to assist the Kidney Paired Donation Program

- Why?
- Centers refusing donors from other centers because they did not do the “right” tests or because the results were “out of range”
- Delays in surgery because of need to do additional tests
Testing: differences between centers

Some centers required tests that others considered unnecessary:

- SPEP(3)
- CRP
- ANA
- TSH
- Ferritin
- Urine calcium, sodium, etc.
Testing: differences in acceptance criteria

- UHN: GFR must be $> 90 \text{ ml/min/}1.73\text{m}^2$
- Other centers: GFR must be $> 80 \text{ ml/min/}1.73\text{m}^2$
- Another proposal: $>75 \text{ ml/min/}1.73\text{m}^2$

- Many such controversies
How Did We Go About It?

- LDAC asked Bob Richardson to chair the “working group” to come up with recommendations
- Created focussed areas for study with a chair; members could be in more than one group
- General Health
- Infection
- Malignancy
- Cardiovascular risk
- Kidney Assessment
- Medical and Social Questionnaire

Once the groups were established, I headed to the golf course, awaiting their reports
Methodology

- Summarized practices of all Canadian Living Donor Programs (environmental scan)
- Reviewed Health Canada requirements
- Reviewed UNOS, UK and ANZA published guidelines
- Limited review of literature when indicated
  - Example: should an SPEP be done?
  - A recent international consensus conference addressing this topic recommended against routine screening for monoclonal gammopathy in health adults
The Process

- Each working group created a draft proposal which was brought to the whole group, debated and discussed
- And discussed
- And discussed
- Then we had a much larger meeting including invited experts from across Canada (nephrologists, transplant specialists, surgeons, social workers, ethicists) to again discuss the document over a 2 day meeting
- Close to final draft created (2014)
- Sent to editor to make it suitable for publication
- Published as a Supplement in *Transplantation* Oct 2015
- Webinars to review the protocol across Canadian sites
What it Will Mean

- Living donor programs wishing to participate in the Kidney Paired Donation program must comply with the recommendations
- There is a system available to approve “outliers”
- The harmonization protocol is only intended to apply to potential donors participating in the Kidney Paired Exchange program – individual sites may choose to adopt it internally
What Tests Are Required?

- Health Questionnaire
- Blood tests
- 24 h urine
- Other urine tests
- Imaging
- Age-appropriate cancer screening

- Visits with coordinator, social worker, nephrologist and surgeon
- May take 2-8 weeks
Blood Tests

- **Chemistry**: Na, K, Cl, CO₂, Ca, P, ALP, urea, urate, albumin, AST or ALT, bilirubin, FBG X 2, A1C, fasting lipids, Creatinine X 2

- **Hematology**: CBC and INR/PTT.

- **Infectious diseases**: screening tests for HIV, HTLV-I, HTLV-II, HBsAg, HBcAb, HCV, CMV, EBV, and syphilis.

- **blood group and HLA**
Urine Tests

- Urinalysis X 2
- Urine culture
- Urine albumin/creatinine ratio
- 24 h urine for creatinine clearance and protein
Imaging

- Chest
- CT angiogram of the abdomen focussing on renal vascular anatomy
- Renal scan not required unless needed for GFR measurement
Other Common Testing (Optional)

- Oral GTT
- Cystoscopy/ kidney biopsy if hematuria
- Cardiac stress testing
- Genetic testing if familial kidney disease
Some of the Highlights and Controversies

#1 – GFR acceptance guidelines

- Heated debate
- Members accused of being overly conservative (paternalistic) and overly liberal (risking patient’s lives!)
- The resolution came from Amit Garg’s group:
- Age-dependent GFR guidelines:

<table>
<thead>
<tr>
<th>Age</th>
<th>GFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30</td>
<td>≥90</td>
</tr>
<tr>
<td>31-40</td>
<td>≥85</td>
</tr>
<tr>
<td>41-65</td>
<td>≥80</td>
</tr>
<tr>
<td>&gt;65</td>
<td>≥75</td>
</tr>
</tbody>
</table>
Malignancy

- Follow screening guidelines from Canadian Cancer Society
TB Skin Tests

- Very controversial
- Western Provinces screen; Eastern Provinces don’t
- Related to relative aboriginal populations

Decision:

Tb skin test only to be done in high risk populations:

- Aboriginals
- Immigrants from endemic areas
- Any other high risk situation
Toxemia

• Now recognized as an important risk factor for cardiovascular disease
History of Toxemia in Pregnancy

Exclusions for Donation

1. Premenopausal potential donor with a history of toxemia in pregnancy <10 years ago.

2. Potential donor with a history of toxemia in pregnancy in recurrent pregnancies.

3. Premenopausal potential donor with a history of toxemia in pregnancy and whose family is incomplete.
A Difficult Case

- 28 year old Hispanic female wants to donate to her mother
- Mother has type 2 diabetes and diabetic nephropathy
- Daughter:
  - BP 135/85
  - BMI 31
  - FBG 6.2 and 6.3 mmol/L
  - TC 6.1, TG 2.8, HDL 0.8, LDL 4.7
Metabolic Syndrome

Living kidney donation is contraindicated in a potential donor diagnosed with metabolic syndrome.

- type 2 diabetes; IGT; impaired FBG; insulin resistance
  AND any two of the following conditions:

  - BP ≥140/90 mmHg;
  - dyslipidemia: triglycerides ≥1.695 mmol/L and HDL-C ≤0.9 mmol/L (male) or ≤1.0 mmol/L (female); central obesity:
    - waist to hip ratio >0.90 (male) or >0.85 (female), or BMI >30 kg/m²;
  - microalbuminuria: urinary albumin excretion ratio ≥20 μg/min or ACR ≥30 mg/gm
Hypertension
Acceptance Criteria

1. Normotensive potential donor.

2. Hypertensive:
   - 50 years of age or older
   - controlled BP on one antihypertensive
   - no other additional cardiovascular or metabolic risk factors.
Medical and Social History

1. Medical and Social History Questionnaire (MSHQ)

2. 30-Day MSHQ

3. MSHQ Rationale Document

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>MSHQ Question #</th>
<th>30DQ Question #</th>
<th>RATIONALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have an intended recipient (someone you want to donate to)?</td>
<td>1a</td>
<td>N/A</td>
<td>Information to determine to whom the potential donor intends/wishes to donate.</td>
</tr>
<tr>
<td>If Yes, what is the recipient’s name?</td>
<td>1b</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>What is your relationship to the intended recipient? (Please be specific.)</td>
<td>2</td>
<td>N/A</td>
<td>Information to determine to whom the potential donor intends/wishes to donate.</td>
</tr>
<tr>
<td>Non-Directed Donors Only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>As a non-directed donor, what are your expectations about having contact with the recipient?</td>
<td>3</td>
<td>N/A</td>
<td>Information about the potential donor’s expectations regarding contact with the recipient.</td>
</tr>
<tr>
<td>Would you want to have contact with the recipient?</td>
<td>4</td>
<td>N/A</td>
<td>Information about the potential donor’s expectations regarding contact with the recipient.</td>
</tr>
</tbody>
</table>
Physical Examination Form

Part 1: To Be Completed By a Licensed Medical Practitioner for All Potential Donor Physical Examinations

<table>
<thead>
<tr>
<th>Assess for the following:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexplained lymphadenopathy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexplained mass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexplained mucocutaneous lesions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Needle tracks or other signs of injection drug use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active infections of clinical significance</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Psychosocial Assessment

#### Support for Decision to Donate

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
<th>Additional Information/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussed plan with proposed recipient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recipient expresses gratitude/appreciation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family supports decision to donate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work/school supportive</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Decision to Donate/Informed Consent

| Statement                                                      | Yes | No | Additional Information/Comments |
|                                                               |-----|----|----------------------------------|
| Appears to have capacity to decide about donation             |     |    |                                  |
| Informed, voluntary decision                                  |     |    |                                  |
| Consistent with potential donor’s values                      |     |    |                                  |
| Indication of internal coercion                               |     |    |                                  |
| Indication of external coercion                               |     |    |                                  |
### Surgical Review Form

- To be uploaded to the donor record for surgical review and clearance by the matched centre.

<table>
<thead>
<tr>
<th>Characteristics of Left or Right Kidney:</th>
<th>Left Kidney</th>
<th>Right Kidney</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length × Width × Height (cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arteries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length to first branch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preaortic/Retroaortic (left)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ureters</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Common Exclusion Criteria

- BMI > 35
- Heart disease, stroke, PVD
- Diabetes
- Addiction
- Active kidney stones
- Proteinuria
- Metabolic syndrome
Donor Outcomes

- Excellent!
- Life expectancy above average
- Risk of kidney failure below average
- No change in lifestyle
- Psychological benefits
- Follow-up annually with family physician