

# The KPD Protocol

## Assessment of Living Donors in Canada

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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:**

David Landsberg (Chair)

Maureen Connelly

Christine Dipchand

Amit Garg

David Grant

Isabelle Houde

Olwyn Johnston

Dale Lien

Ruth McCarrell

Rahul Mainra

Thomas Mueller

Peter Nickerson

Christine Pippy

Robert Richardson

Leroy Storsley

Linda Wright

Serdar Yilmaz

Kimberly Young

## **Canadian Blood Services:**

Tracy Brand

Debra Cadelli

Dena Rice

Bryan Sandilands

PJ Vankoughnett-Olson

Kathy Yetzer

# 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  $> 90 \text{ ml/min/1.73m}^2$
- Other centers: GFR must be  $> 80 \text{ ml/min/1.73m}^2$
- Another proposal:  $>75 \text{ ml/min/1.73m}^2$
  
- 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, CO<sub>2</sub>, 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 andHLA

# 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:

Age	GFR
18-30	≥90
31-40	≥85
41-65	≥80
>65	≥75

# 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  $\geq 140/90$  mmHg;
  - dyslipidemia: triglycerides  $\geq 1.695$  mmol/L and HDL-C  $\leq 0.9$  mmol/L (male) or  $\leq 1.0$  mmol/L (female); central obesity:
  - waist to hip ratio  $>0.90$  (male) or  $>0.85$  (female), or BMI  $>30$  kg/m<sup>2</sup>;
  - microalbuminuria: urinary albumin excretion ratio  $\geq 20$   $\mu\text{g}/\text{min}$  or ACR  $\geq 30$  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

### Medical and Social History Questionnaires (MSHQs) – Rationale Document

#### General Questions About Donation

QUESTION	MSHQ Question #	30DQ Question #	RATIONALE
Do you have an intended recipient (someone you want to donate to)?	1a	N/A	Information to determine to whom the potential donor intends/wishes to donate.
If Yes, what is the recipient's name?	1b		
What is your relationship to the intended recipient? (Please be specific.)	2	N/A	Information to determine to whom the potential donor intends/wishes to donate.

#### Non-Directed Donors Only

QUESTION	MSHQ Question #	30DQ Question #	RATIONALE
As a non-directed donor, what are your expectations about having contact with the recipient?	3	N/A	Information about the potential donor's expectations regarding contact with the recipient.
Would you want to have contact with the recipient?	4	N/A	Information about the potential donor's expectations regarding contact with the recipient.

# Physical Examination Form

## Physical Examination Form

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

Gender:  Male  Female

Assess for the following:

- Unexplained lymphadenopathy  Yes  No
- Unexplained mass  Yes  No
- Unexplained mucocutaneous lesions  Yes  No
- Needle tracks or other signs of injection drug use  Yes  No
- Active infections of clinical significance  Yes  No

## Appendices

# Psychosocial Assessment

### *SUPPORT FOR DECISION TO DONATE*

Statement	Yes	No	Additional Information/Comments
Discussed plan with proposed recipient	<input type="checkbox"/>	<input type="checkbox"/>	
Recipient expresses gratitude/appreciation	<input type="checkbox"/>	<input type="checkbox"/>	
Family supports decision to donate	<input type="checkbox"/>	<input type="checkbox"/>	
Work/school supportive	<input type="checkbox"/>	<input type="checkbox"/>	

### *DECISION TO DONATE/INFORMED CONSENT*

Statement	Yes	No	Additional Information/Comments
Appears to have capacity to decide about donation	<input type="checkbox"/>	<input type="checkbox"/>	
Informed, voluntary decision	<input type="checkbox"/>	<input type="checkbox"/>	
Consistent with potential donor's values	<input type="checkbox"/>	<input type="checkbox"/>	
Indication of internal coercion	<input type="checkbox"/>	<input type="checkbox"/>	
Indication of external coercion	<input type="checkbox"/>	<input type="checkbox"/>	

## Appendices

# Surgical Review Form

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

In Press – Not For Distribution

## Living Kidney Donor Surgical Review Form

### Donor Demographics:

Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Blood Type (ABO): \_\_\_\_\_

Height (cm): \_\_\_\_\_ Weight (kg): \_\_\_\_\_ BMI: \_\_\_\_\_

Renal function (total): GFR \_\_\_\_\_ mL/min/1.73 m<sup>2</sup> or CrCl \_\_\_\_\_ mL/min

### Characteristics of Left or Right Kidney:

	Left Kidney	Right Kidney
<b>Dimensions</b>		
Length x Width x Height (cm)		
<b>Arteries</b>		
Number		
Length to first branch		
<b>Veins</b>		
Number		
Length		
Preaortic/Retroaortic (left)		
<b>Ureters</b>		

# 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