

# **Saskatchewan Renal Transplant Program** **Review**

July 9th, 2010

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for the Saskatchewan Transplant Program Steering Committee

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## **A. Executive summary and recommendations**

Kidney transplantation represents the preferred mode of treatment for end-stage kidney failure, as successful kidney transplantation improves patient survival compared to conventional dialysis. Therefore, any issue that limits transplantation results in reduced survival of patients with kidney failure and not solely reduced quality of life. The Saskatchewan kidney transplant program has successfully transplanted hundreds of patients and provided to them improved quality of life and prolonged survival. The program, while successful, has existed in an isolated manner largely driven to its successes by the dedication of key individuals and the support of a large number of skilled surgeons, pathologists, radiologists, nurses, coordinators, lab staff, and administrators. The somewhat abrupt cessation of transplant activity following the health issues of a single surgeon reflects the precarious nature of the transplant program as it existed. Issues apart from surgery have an equivalent capacity to eventually limit or suspend the program. In particular, the long-term viability of transplant nephrology and deficiencies in the HLA laboratory would have required attention even if surgical issues were not present.

The reviewers were impressed by the enthusiastic response of the transplant program members, staff, administration and the Ministry of Health to identify and address the issues pertinent to the long-term sustainability of the transplant program, in order to resume transplantation within Saskatchewan. Overwhelmingly, there was support for maintaining and enhancing a kidney transplant program within Saskatchewan. All viewed transplantation out of province has a nonviable long-term solution. The reviewers and members also recognized that resolution would require both short-term and long-term planning to restart renal transplantation effectively in Saskatchewan. Immediate return to transplantation to its state prior to July 2009, in the absence of addressing all the issues, was recognized as a scenario that would likely result in failure. This would be detrimental to the health of patients and as well public perception of transplantation in Saskatchewan. It is of *great* concern that the current public perception of problems within the transplant program may have translated to decreased deceased donor numbers within Saskatchewan. If lower donor numbers persist, patients in Saskatchewan will suffer longer times on dialysis with resultant decreased survivals. There is no out of province solution that will address or improve donor numbers within the province of Saskatchewan. It is therefore paramount that action is taken.

Based on the review of data, the extensive interviews we conducted, and experience in our and other programs, we recommend that a provincial kidney transplant program in Saskatoon remains the preferred model for care. However we recommend that substantial changes occur in the short and long-term to ensure that the program is sustainable and assumes its previous national stature of excellence.

**Recommendations:**

1. Transplant numbers are related to donor rates. Therefore, there must be immediate attention to misconceptions regarding *Saskatchewan* donors and their utilization for *Saskatchewan* patients, despite current transfer of patients to Alberta. This includes education of staff and physicians in intensive care units and emergency departments, as well as positive media stories. Donor numbers need to increase immediately. The transplant program in Saskatchewan has had a temporary setback and is on track, but requires public support in the form of altruistic donation.
2. The quality of a transplant program, maintenance of competency and excellent outcomes does not require volumes substantially higher than the volumes prior to July 2009. There is support and infrastructure in place sufficient to restart the living donor transplant program. This initiative can be planned well in advance and would not stress current surgical support. The resumption of deceased donor transplants within Saskatoon without changes in surgical personnel, however would stress surgical support. Until changes are made in Saskatoon, our recommendation would be to continue with the Edmonton collaboration until a stable model in Saskatoon can be agreed upon.
3. Highly sensitized and more complex patients need to be served by Edmonton. As this does not represent the majority of waitlisted Saskatchewan patients, patients could be reviewed in Edmonton prior to transplant, and patient management pre-and post-transplant could be agreed upon between Edmonton and Saskatoon. There is considerable experience with high-risk immunological patients in Saskatoon, and the previous significant limitation in immunological follow-up by the HLA Lab has been addressed. Again, Edmonton would have to accept cross matching results as well as antibody determination by Saskatoon. Regardless, it would *not* be either fair or beneficial to carry on a system in which only some Saskatchewan patients received an opportunity to have a renal transplant.
4. Both nephrology and surgery require transplant champions. In the case of nephrology, Dr. Shoker will be in place to continue his excellent care of transplant patients, carry out administration of transplant nephrology, and to eventually transition his responsibilities to younger faculty. Currently, there is no identified surgical champion of transplantation, and this needs to be addressed immediately. The administration of the transplant program requires co-management by both surgery and medicine. While new recruits may serve in this co-management as well as being future champions within surgery, the Department of Surgery needs to identify at least an interim champion. Several names were discussed. The interim surgical director could be identified from either vascular surgery or urology.

5. The preferred model of transplantation would be to have dedicated kidney transplant urologic surgeons who are able to perform the anastomosis and ureteric implantation as well left laparoscopic donor organ retrieval. The existing urologist who can perform the laparoscopic donor nephrectomy is near retirement, but still participates in the living donor program. There are well-trained individuals that are currently undergoing transplant training in Canada and may be available soon. However, the environment must be made attractive for such recruits, which includes financial incentives in order to permit clinical and research dedication to transplantation, rather than participating extensively in general urology to maintain a reasonable income. A transplant surgeon is unlikely to maintain a reasonable income solely on transplant activity, and thus new funding must be found. As well, there needs to be consideration of required on-call time and activity, a factor which has led to the current suspension of the transplant program. A critical number of transplant surgeons would be 2, and additional support would be required from the current structure of vascular surgery and urology to perform transplants, as needed on an on-call basis. It was clear that dedicated renal transplant surgeon(s) would be able to provide stability to the Transplant Program, by maintaining call coverage, continuing the laparoscopic donor nephrectomy program, and exploring methods to increase donor rates (ie. donation after cardiac death kidney transplantation).

The immediate recruitment of a dedicated transplant surgeon would be possible by **aggressive** attraction strategies, both environment and financial. A second transplant surgeon would be a longer-term goal as the vascular surgery and urology support could transition for a second recruit over the next several years.

6. A sustainable transplant program must have its foundation in an academic program. There are no models currently in Canada in which transplantation is solely based on a service component, and all have an academic basis in the form of research, teaching of fellows, and administration. An academic program as defined by the University requires 5 personnel which would ideally be blended between transplant surgeons and transplant nephrologists. Therefore 4 academic positions would be required in addition to the existing position held by Dr. Shoker. However, although the Dean of Medicine is in support of an academic program in transplantation along with Departments of Medicine and Surgery heads, the 5 academic personnel need to reside within departments. Medicine and Surgery therefore need to identify 5 existing or recruited individuals within respective departments that fit the academic criteria to obtain University support. The Dean may be able to obtain funding for these positions through the Ministry of Health.

7. The Departments of Medicine and Surgery (as well as Pathology) need to adopt a greater accountability/responsibility for the transplantation program. This includes a dual reporting structure by the Medical as well as the proposed Surgical Directors of Transplantation to their respective department chairs. Department chairs need to be engaged in transplantation to remain vigilant to

future *opportunities* as well as *threats*. These departments also need to contribute to the environment of new recruits including mentoring, space, and finances. If a successful Alternate Funding Program (AFP) emerges within Saskatchewan, there should be priority given to the support of the transplant program. As well, within the Division of Nephrology, given the importance of transplantation to the academic success of nephrology and development of a Royal College-approved training program, there should be greater integration. This includes stabilizing financial support of the transplant nephrologists, and certainly support for transplant clinics and assessments. For example, donor assessments should be provided by independent non-transplant members of the division of nephrology. Donor assessments by transplant nephrologists have perceived conflict of interest and generally this situation is not desirable.

8. The Ministry of Health should consider a model of consolidated funding for renal transplantation, which covers the recruitment of transplant surgeons and support of transplant nephrologists, as well as funding for translational research that enhances transplant outcomes. This consolidated funding should also include current costs for all parts of transplant which will allow long term projected costs. The administration, control and responsibility of the consolidated funding as related to the medical staff and establishing the academic program should reside with the co-directors but audited by appropriate hospital administration. Such models that currently exist within Canada have demonstrated benefit, with such centers being recognized for clinical and research excellence, innovation of transplant care, as well as retention of staff and greater ability to recruit.

9. It was clear from the review that communication and collaboration between Medicine, Surgery, Laboratory Medicine (HLA lab) could be improved. Regular meetings (ie monthly) with expected if not mandatory attendance of surgeons/ physicians/ lab directors/ coordinators should be planned. This should be one of several action items that would foster bonds between the members of the transplant program, promote communication and allow opportunities for research collaborations within and between groups.

## **B. Background and terms of reference**

The Saskatchewan Transplant Program is a provincial program centered in Saskatoon, for the retrieval, processing and implantation of tissues and organs. The Saskatoon Health Region services the administrative and operational needs for this provincial program, which includes renal transplantation within the province as well as non-renal solid organ transplants out of province. In addition to Saskatoon, significant funding is provided to satellite clinics in Regina. This supports the principle of having kidney transplant care provided within the province with a minimized travel burden.

The Saskatchewan transplant program has been an important component of the Department of Medicine and the Nephrology Centre of Excellence, and has had dedicated support from St. Paul's Hospital and its foundation since the amalgamation of all renal services in 2001. Transplantation has also been heavily supported by the Department of Surgery. Both Vascular Surgery and Urology have provided the surgical component of transplantation. The program was established in 1989 and with provincial support and donation efforts by the Saskatoon program, has seen a gradual increase until 2009, in both donor numbers and transplants. Growth in numbers has also been accompanied by a modest increase in support staff, as well as additional nephrologists. There has not been an increase in surgical staff in this same time period.

After 20 years of operation, the renal transplant program was abruptly suspended in the summer of 2009, following the temporary illness of a key surgeon. This was also concurrent with identified deficiencies in the HLA lab which required remedial solutions. Since July 2009, transplant patients from Saskatchewan have been transported to Edmonton for kidney transplant surgery with follow-up upon return to Saskatoon or Regina. The suspension of kidney transplant surgery has had a major public effect. It is not known whether this has eroded the confidence of the public and the patients waiting for transplantation. It has reduced the morale of many of the current transplant program members. It has duplicated costs, since payments at the inter-provincial rate have gone to Alberta while existing infrastructure in Saskatchewan has been maintained. Finally, it has reduced a previously viable program to essentially out patient nephrological follow up clinics. Patient follow-ups since 2009 include transplants previously successfully transplanted in Saskatoon as well as those recently transplanted in Edmonton. The suspension of surgery and consequent review has highlighted the precarious nature of the program which extends beyond issues of surgical support that has existed for years, but also non-surgical components of the program including governance and reporting structures and the HLA laboratory.

It would be important to note that the Ministry of Health as well as *all* members of the transplant program are enthusiastically committed to transplant support of dialysis patients within the province and finding solutions to the problems of the Saskatchewan Transplant Program.

***The purpose of this review is to examine the current medical-surgical delivery of kidney transplant care and to advise and recommend on a sustainable model and supporting infrastructure for the Saskatchewan Renal Transplant Program.***

## **C. Structure of review**

- **Steering committee** made up of representatives from the Departments of Surgery (Chair), Medicine and Laboratory Medicine
- Two senior administrative heads
- Nephrology
- Surgery
- St. Paul's Hospital
- Ministry of health

### • **External Consultants**

Dr. Anthony Jevnikar  
 Professor of Medicine, Surgery, Microbiology & Immunology  
 Director Transplantation Nephrology 1998-present  
 Co-director Multi Organ Transplant Program 2009-present  
 London Health Sciences Centre, London, Ontario  
 Past president Canadian Society of Transplantation (2004-2006)  
 Board member American Society of Transplantation (2009-2012)  
 Member of the American Society of Transplantation and American Society of Transplant Surgery Joint Council (2009-2012)

Dr. Patrick Luke  
 Associate Professor of Surgery  
 Surgical Director Kidney Transplantation,  
 Co-director of Multi Organ Transplant Program (MOTP) 2009-present  
 London Health Sciences Centre, London, Ontario

## **D. Components of the Program**

*Note \* indicates that they were interviewed in person or by teleconference.*

### **(a) Personnel**

#### **(i) Nephrology**

- **Dr. Joanne Kappel \***  
**Division Head, Nephrology and Deputy Head, Department of Medicine**, Saskatoon Health Region and Clinical Professor, College of Medicine, University of Saskatchewan BSc(Biology), MD, FRCPC Int Med (U of S) 1988, Nephrology (UofT) 1990 Start date with SHR: June 28, 1990. Transplant Program since 1991. Clinical: 60%, administration:



- 20%, teaching: 20%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching.
- **Dr. Ahmed Shoker \***  
**Medical Director, Saskatchewan Transplant Program and Nephrologist, Department of Medicine,** Saskatoon Health Region and Professor, College of Medicine, University of Saskatchewan MBChB, FRCPC Int Med (UBC) 1987, Nephrology (UWO) 1988 Start date with SHR: January 1, 1992. Transplant Program since 1992 and Medical Director since 1995. Clinical: 40%, research: 40%, teaching: 10%. Full academic salary and practice plan fee for service.
  - **Dr. Rahul Mainra \***  
**Transplant Nephrologist, Department of Medicine,** Saskatoon Health Region and Clinical Assistant Professor, College of Medicine, University of Saskatchewan BSc, MD, FRCPC Int Med (UofS) 2003, Nephrology (UWO) 2005, Renal Transplantation (University of Sydney) 2008 Start date with SHR: July 1, 2008. Transplant Program since 2008. Clinical: 85%, teaching: 15%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching.
  - **Dr. Abubaker Hassan**  
**Transplant Nephrologist, Department of Medicine,** Saskatoon Health Region and Clinical Assistant Professor, College of Medicine, University of Saskatchewan MBBCh, FRCP(C) Int Med (UWO) 2005, Adult Nephrology (UWO) 2006, Kidney Transplant (UWO) 2007. Start date with SHR: September 1, 2007. Transplant Program since 2007. Clinical: 85%, teaching: 15%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching.
  - **Dr. R. Baltzan**  
**Nephrologist,** Private practice transplant nephrology.

## (ii) Urology

- **Dr. Peter Barrett \***  
**Laparoscopic Urologist, Division of Urology, Department of Surgery,** Saskatoon Health Region MD, FRCSC Urology (UofT) 1975 Start date with SHR: January 1, 1976. Transplant Program since 1989. Clinical: 100%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching concurrent with clinical service. *Planned retirement in the next 12- 24 months.*
- **Dr. Kishore Visvanathan \***  
**Division Head, Urology, Department of Surgery,** Saskatoon Health

Region (SHR) and Clinical Professor, College of Medicine, University of Saskatchewan MD, FRCSC Urology (Univ of Ottawa) 1991  
 Start date with SHR: February 1, 1992. Transplant Program since 1992.  
 Clinical: 95%, teaching: 5%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching.

The following urologists participate in the deceased donor transplant program in the retrieval of kidneys and ureteric implantation (in almost all cases after the vascular surgeon has completed the anastomoses) on an 'on-call' rotation.

- **Dr. Donald Fentie**  
 BSc, MD, FRCSC Urology (Laparoscopy), (Univ of Alberta) 1984  
 Start date with SHR: January 1, 1985
- **Dr. Saul Gonor**  
 MD, FRCSC Urology (Univ of Alberta ) 1983  
 Start date with SHR: January 1, 1984
- **Dr. Kunal Jana**  
 MD, FRCSC Urology (Univ of Ottawa) 2006  
 Start date with SHR: September 1, 2006
- **Dr. Peter Lau**  
 MBBS, FRCS(Edin) 1991, FRCSC Urology (Dalhousie) 1997  
 Start date with SHR: November 15, 1997
- **Dr. Shari McKinny**  
 MD, FRCSC Urology (Univ of Alberta) 2007  
 Start date with SHR: August 20, 2007
- **Dr. Larry Taranger**  
 MD, FRCSC Urology (Univ of Toronto) 1970  
 Start date with SHR: December 11, 1975
- **Dr. Paul Weckworth**  
 MD, FRCSC Urology (Univ of BC) 1985  
 Start date with SHR: May 27, 1987

### **(iii) Vascular Surgery**

- **Dr. Brian Ulmer \***  
*Division Head, Vascular Surgery, Department of Surgery*, Saskatoon Health Region (SHR) and Community Faculty, College of Medicine, University of Saskatchewan BSc(Adv), MD, FRCSC Gen Surg (UofS) 1988, Vascular Surg (UofM) 1990. Start date with SHR: June 27, 1990.

Transplant Program since 1990. One year preceptorship for deceased donor and two year preceptorship for living related donor. Clinical: 70%, administration/teaching/research: 30%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching.

- **Dr. Jodi Spelay**  
**Vascular/General Surgeon, Department of Surgery,** Saskatoon Health Region MD, FRCSC Gen Surg (UofS) 1998, Vascular Surg (UofM) 2000, Endovascular (Vanderbilt) 2000. Start date with SHR: July 1, 2000. Transplant Program since 2000. One year preceptorship for deceased donor and two year preceptorship for living related donor. Clinical: 90%, teaching: 10%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching.
- **Dr. Bruce DuVal**  
**Vascular/General Surgeon, Department of Surgery,** Saskatoon Health Region MD, FRCSC Gen Surg (UofM) 1992, Vascular Surg (UofM) 1994 Start date with SHR: December 1, 1994. Transplant Program since 1994. One year preceptorship for deceased donor and two year preceptorship for living related donor. Clinical: 90%, teaching: 10%. Compensation is fee for service for clinical work and community faculty hourly stipends for teaching.

#### (iv) HLA laboratory

- **Dr. Qingyong Xu \***  
**Scientific Director, HLA Laboratory,** Saskatoon Health Region and Clinical Assistant Professor, College of Medicine, University of Saskatchewan. BS Biochemistry (China) 1998, MS Developmental Biology - Molecular Genetics (China) 2001, PhD Transplant Immunology (University of Wisconsin-Madison) 2007. Start date with SHR: December 10, 2007. Transplant Program since 2007. Clinical: 60%, research: 30%, teaching: 10%. Full salary through SHR.
- **Dr. Jianping Li \***  
**HLA Consulting Director, HLA Laboratory,** Saskatoon Health Region; based in Ottawa, Ontario. Purely clinical, his role is to serve as the director of the laboratory until such time as Dr. Xu is qualified and prepared to take over the function of director.

#### (v) Other Clinical Transplant Support

##### **Department of Radiology and Medical Imaging**

- **Dr. Mark Shenouda \***

**Pathology**

- **Dr. Rajni Chibbar \***

**Department of Medicine Chairman**

- **Dr. Vernon Hoepfner \***

**Department of Surgery Chairman**

- **Dr. Alan Casson\***

**(vi) Administration**

- **Ms. Shan Landry**  
***Vice President Community Services***, Saskatoon Health Region  
Responsibilities of this role include oversight of all health related community service delivery programs including Mental Health & Addictions, Home Care, Long Term Care, Primary Health, Public Health and Chronic Disease Management and Renal Services.
- **Dr. David Poulin \***  
***Vice President Medical Affairs***, Saskatoon Health Region  
(Position also known as Senior Medical Officer)  
Responsibilities of this role include medical administration, recruitment/retention, credentialing, alternate funding, medical quality and discipline. All department heads report to this position for medical administrative matters. Joined the Saskatoon Health Region in May 2007. Clinical background in family medicine and full time emergency medicine.
- **Ms. Donna Bleakney \***  
***Director of Chronic Disease Management & Renal Services***,  
Saskatoon Health Region (Reporting to Shan Landry) Responsibilities include oversight of a number of CDM programs (Live Well – Education, chronic conditions, Respiratory, TB, etc.) and Renal Services – (Hemodialysis Incentre, Community Renal Health Centre, Saskatchewan Transplant Program, Home Based Therapies, Chronic Renal Insufficiency and Plasmapheresis Program)
- **Ms. Raylene Matlock \***  
***Manager Saskatchewan Transplant Program***  
(Reporting to Donna Bleakney). Responsibilities include oversight of all transplant programs including kidney, heart, lung, liver, the Pulmonary Hypertension Program of Saskatchewan, the surgical bone bank, tissue and solid organ donation. This also includes the clinical operation of the

Regina office. The Saskatchewan team includes transplant coordinators, social workers, pharmacists and administrative staff.

- **Judy Archer \***, Director Laboratory Medicine Saskatoon Health Region (SHR)
- **Maureen Ffoulkes-Jones\***, Manager Laboratory Medicine SHR
- **Jenny Bartsch\***, Director Surgery Services SHR
- **Deb Hicks \***, Manager of Nursing Operating Room St. Paul's Hospital SHR

The Saskatchewan Transplant program is a provincial program administered by Saskatoon Health Region for the province. Ministry personnel directly involved in the review and provincial coordination are:

**Mr. Patrick O'Byrne**

***Director of Community Hospitals and Specialized Services***

Acute and Emergency Services Branch Ministry of Health

**Ms. Deborah Jordan \***

***Executive Director of Acute and Emergency Services Branch*** Ministry of Health

**(b) Transplant Unit:** There is no dedicated transplant unit currently at St. Paul's Hospital, and all post transplant patients are followed on 6 Medicine. One room has been reserved in the past for transplant patients but this has not been used for transplant patients since summer of 2009. There is an attempt in the nursing roster to schedule nurses with transplant experience when transplant activity occurs. There are no nurse practitioners for transplant specifically but there are transplant experienced pharmacists and social workers in the program.

**(c) Operating rooms:** There are no dedicated transplant operating rooms and OR time is received from primarily vascular surgery time. One case was reported to the reviewers of a kidney that was lost due to prolonged storage times, which resulted from emergency cases that continually delayed the transplant. The incident was reviewed internally by surgery, and while there was no formal recommendations, the incident brought attention to the problem sufficiently that no subsequent similar cases have occurred since that time. Although not published, the reported cold-ischemic times for the Saskatoon transplant program are reasonable. Overall, there does not appear to be a major obstacle in transplantation from operating room time scheduling at the volumes, prior to the program suspension in 2009.

## **E. Donor rates, sources, and performance**

Transplant volumes are determined in large part by donor numbers. Currently using CIHI data (2005-2009), Saskatchewan transplants 20.8 patients per million population (PMP). This compares to the national average of 21.1 PMP and a range of 13.4-27.3 PMP in the various provinces. The current number of patients waiting is 106, which is unchanged from 2009 and slightly up from the 97 in 2008. There was an increase in transplant numbers from 2006 to 2007. The time to transplant was approximately 18 months with all ABO blood groups, which is substantially shorter than most centers in Canada. In comparison, wait times in Ontario would be in the range of more than 4-5 years. However, the wait times in Saskatchewan will change as a result of transfer of patients to Edmonton for transplants, due to reduced donation rates, and the fact that the surgically and immunologically complicated patients would continue to sit on the waiting list.

The source of donor kidneys is primarily from deceased donors with 23 deceased donors and 13 living donors in the last full calendar year of transplantation in Saskatoon (2008). In 2009, 19 deceased donors and 3 living donors were transplanted from January to July, at which time recipients were transferred to Edmonton. There appeared to be some activity in 2010 with a total of five transplants to from January to March 2010. The average number of transplant donors has been approximately 14 per million, which is close to the Canadian average, but significantly less than some high-performing regions in Canada which consistently reach 24 to 25 per million. The potential number that could be achieved in Saskatchewan is unknown, as many factors affect suitability of deceased donors, but it is likely that donor numbers are substantially less than what could be achieved in the province. In the United States with a collaborative effort, rates of 27 to 28 per million were achieved. Similar rates could be achieved in Saskatchewan. Approximately 80% of the current deceased donors would be considered standard criteria donors while the remaining 20% would have expanded criteria characteristics, associated with higher risk for delayed graft function and shortened graft survival. The percentage of expanded criteria donors has generally increased throughout Canada, and may be occurring in Saskatchewan. The use of expanded criteria donors requires greater input by surgery for acceptance criteria, and could increase resource requirements for recipients, with more surgical intervention, radiological support, pathology support, and longer lengths of stay. The conversion rate for organ donors is higher in Saskatoon than in Regina which also has a very low request rate of 5%. Conversion rate targets should be approximately 80% and currently they are half that. There is no mandatory request in place in Saskatoon or Regina. Donation after cardiac death has been discussed and several intensive care physicians were informally identified as potential champions. With establishment of protocols, dedicated intensive care physicians and a transplant program with adequate surgical and nephrology support, donation after cardiac death donors could represent a substantial increase in the number of donors with post transplant outcomes superior to expanded criteria donor organs.

Donor coordinators are shared between all solid organs. There is a division between living donor and deceased donor co-ordinator staff. Pulsatile perfusion is used for maintenance of organs and the average cold ischemia time at 12 hours is excellent. There are standard operating protocols for procurement, storage and transport of donor kidneys that exist. There are standard operating protocols for reporting adverse events such as transmission of infectious organisms as required by Health Canada.

*There is no donor management committee that audits conversion rates and best practice guidelines for organ and tissue donations in the region. This committee should be chaired by an intensive care physician (Dr. Mark James had been identified) with attendance of surgeons, administrators, and donor co-ordinators.*

The discussion of whether to accept an expanded criteria donor kidney is left to the nephrologists on-call and there is no separate list for such donors. There has been a substantial decrease in the donor rates over the past one year and has dropped to below 10 per million. While other provinces may have similarly had decreased numbers, it is likely that perceived problems within the transplant program have influenced the donor rates. There is Canadian experience with “negative press” in a transplant program leading to reduced donor rates. It is not known whether transportation of patients out of province on a more permanent basis might not have a greater or permanent effect on this reduced donor rate. *Therefore it appears prudent to address the current issues as quickly as possible and to seek when possible, ‘positive press’ for the Saskatchewan transplant program.*

## **F. HLA Diagnostic Laboratory: support and challenges**

A high-quality HLA diagnostic laboratory is essential for the function of a kidney transplant program. The name 'HLA lab' is traditional and in many centers is being replaced with terminology that reflects more accurately its true function, namely 'immunological risk assessment laboratory'. There are two main components of the immunological risk laboratory, including the accurate HLA profiling of both donors and recipients, and as well determining if preformed immunity is present in the form of donor specific antibody (DSA). At a minimum, cross matching requires accurate AHG-CDC testing, but this has been supplemented in most centres by the addition of solid phase testing for preformed antibodies. Luminex and flow cytometry has recently been added to the laboratory.

An extensive report was completed and submitted to the program by Dr. Peter Nickerson in April of 2009. Alarming, this identified serious deficiencies that were potentially placing transplant patients at risk either for rejection by false negative test results or by denying acceptable recipients transplants due to false positive cross match results. Major deficiencies included the absence of a properly trained and ASHI credentialed HLA laboratory director, absence of a proper quality assurance (QA) program and there were also questions of standards of practice and inadequate resources.

A sustainable program unequivocally would require all of the concerns to be addressed and corrected. Addressing these deficiencies and the response of the Saskatchewan transplant program to the report by Dr. Nickerson in detail is beyond the scope of this review. However in the response to the report, the major deficiencies appear to have been addressed. Most importantly Dr. Li has been identified as a properly qualified Consulting Director. Dr. Li is also providing mentoring for Dr. Xu as a "HLA director in training". It is not clear what the division of responsibilities will be, upon successful completion of training and examination of Dr. Xu. In many centres, a transplant physician with clinical expertise and HLA understanding acts as a consultant to the laboratory to bring clinical insights and understanding. Dr. Shoker was not listed as such a consultant, although Dr. Mainra reviews all the living donor paired exchange results with the laboratory. All cross match results are now interpreted by these directors and provided to the medical staff prior to transplantation. Detailed standard operating protocols have been developed, published, and openly available. A quality assurance (QA) program was initiated in October 2009 but is currently incomplete. QA includes ASHI proficiency testing which are now excellent for the Saskatoon laboratory. Despite these improvements and the development of solid phase testing, cross match results using AHG-CDC methods are not accepted by Edmonton and are duplicated. The current utility of the HLA laboratory testing has been to identify low immunological risk patients suitable for transplantation in Edmonton. There is communication of transplant cross match results to the coordinators rather than nephrologists and surgeon on



call directly. This may not be an optimal system for highly complicated patients, as there is required interpretation of negative AHG- CDC cross match in the presence of preformed antibodies detected by flow cytometry or by Luminex technology. For example, there are no standardized forms that list shared HLA antigens with previous donors, nor antibody levels that is transmitted to the nephrologists and surgeon on call. There are desensitization protocols for high-risk recipients but none have been performed recently. Post transplant monitoring of antibody levels is provided to the transplant program and are highly reliable. There was a general sense from the lab that while they were critically important to a sustainable transplant program, that routine communication could and should be improved with the HLA laboratory.

In summary, the HLA laboratory has seriously addressed concerns of the external report from 2009, and is capable of providing excellent support to the Saskatchewan kidney transplant program. The current personnel including the laboratory director, are highly skilled and need to feel a part of the transplant team to encourage retention. Development of research would be highly desirable to foster interest and retention, and would require identification of research lab space as well as collaboration with nephrology and surgery for research projects.

## **G. Transplant Surgery: Support and challenges**

Surgical support for the transplant program is a hybrid model with participation from vascular surgery and urology. Currently, the primary surgical recipient input appears to be from vascular surgery, as they provide the vascular surgical anastomoses, and also review all potential transplant recipients. Urology reviews listed patients with complex urological issues, and provides technical support for ureteric implantation. As well, all donor retrievals are performed by urology in Saskatoon and by general surgery in Regina. One urologist is currently involved with the living donor program and performs all of the laparoscopic donor nephrectomy procedures. There was expressed concern that technical expertise in urological procedures and in particular laparoscopic donor organ retrieval, is under threat due to the imminent retirement of this individual. In most centers, a single surgeon provides both the vascular and ureteric anastomoses - the model in Saskatchewan has evolved to the hybrid roles and is historic in nature. Both the vascular surgeons and urologists are comfortable with the current model, and would be uncomfortable with any shift to a 'single surgeon model'.

*Interestingly, despite their primary importance in transplantation, there are no surgeons listed on the organizational chart for the transplant program.*

The loss of one vascular surgeon due to health issues, resulted in a suspension of the transplant program. This was associated with the large clinical load on the vascular surgeons apart from transplantation, and that the primary focus of the vascular surgery group indeed is to support vascular surgery patients. However they will continue to support (as they have done for many years) the transplant program, as they understand and appreciate the importance of transplantation. Although not all of the vascular surgeons were interviewed, the reviewers were told they would support a model with a dedicated transplant surgeon(s) being primarily responsible for both living and deceased donor transplants, and all the surgical procedures. However vascular surgery would continue to provide surgical support in any model, including one with dedicated transplant surgeons, which would still require on-call scheduling support.

*It is possible that with success of an alternative funding program (AFP) in vascular surgery, a new FTE would facilitate transplant support and alleviate some of the surgical load stress currently in the group. However the addition of a new vascular surgeon would not address all of the current transplant program problems.*

There does not appear to be an opportunity for an additional urologist under an AFP, as urology is not an academic training program. Support for any transplant urologists would require them to be involved in general urology. This is an issue, as the current urologists are relatively young and no retirements are expected apart from Dr. Barrett for the next five years. The Chief of Urology

indicated that they would find a new individual to perform general urology procedures and run a general practice. However, the division will require additional support for operating room availability, clinic time and salary support.

It was noted by the reviewers that complex immunological cases have been performed in the past, but that decisions regarding the immunological suitability, have been left almost exclusively to the transplant nephrologists. This includes patients at high risk of graft loss due to rejection. There are quarterly meetings of the transplant program which includes surgery and nephrology, with variable attendance, in which complex patients are and can be discussed. However the timing of these meetings was felt to be too infrequent and certainly there could be greater communication between members of the transplant program. The issues regarding serious problems in the HLA Lab were of a surprise to the vascular surgery group also reflecting issues of communication.

*There is no transplant surgical database.* Despite their primary involvement in the transplant program, it was noted that both vascular surgeons and urologists were not familiar with surgically relevant transplant statistics in a detailed manner. For example, verified delayed graft function rates, thromboses and ureteric complication rates requiring nephrosotomy tubes were not reported, but might actually be higher than expected. As well, while it was known that the 'target for cold ischemic times' was less than 24 hours, statistics for average cold ischemic times could only be provided by the coordinators. Indeed with an average cold ischemia time of 12 hours (unverified by reviewers), and a target of no greater than 24 hours, the Saskatchewan transplant program has commendable cold ischemic times, which are equal to or better than most programs in Canada. The possibility of using donors following cardiac death (DCD), which in some centers in Canada represents one third of all deceased donor organs, has been discussed within the transplant group. However there have been no formal protocols and no intensive care 'champion' has been identified.

Prior to the suspension of the program, list management, organ donor retrieval and subsequent recipient transplantation appear to function well logistically. For patient listing in which suitability of recipients for activation on the waiting list is reviewed, the primary responsibility appears to be with the transplant nephrologists and their referrals. This was stated to be in concordance with the consensus listing document published by the *Canadian Society of Transplantation* in the *Canadian Medical Association Journal* recently. There are some issues that need to be addressed. Immunosuppressive protocols are generated by nephrologists and are not by consensus within the transplant program. Allocation algorithms are not published. However, all donor organs are placed on pulsatile perfusion, which has been the standard of care for past 3 years. This was forward thinking by the transplant program, as the standard of care in the rest of Canada has only recently included pulsatile perfusion. Organ

allocation and recipient selection is primarily the role of the transplant nephrologists. However there have been cases in which the selected recipients have been turned down by surgery immediately prior to transplantation. Transplant recipients are admitted under nephrology and postoperatively are transferred to a medical floor (6 Med). Although these patients are postoperative, nursing care is by personnel with considerable experience in transplantation and post surgical care. Currently, there appears to be a reasonable morale by nursing staff both in the operating rooms and on the medical floors. However there are concerns regarding the loss of a premiere program in Saskatchewan and confusion as to the underlying reasons. This could erode the morale of staff. *This is of great concern as nurses are integral to any transplant program and contribute not only to the care of patients but also of the promotion of transplantation as an option for donor families and for recipients.*

In summary, the hybrid model of surgical transplant support has provided good support for the transplant program but is not the preferred model. The recruitment or identification of a surgical 'champion' in the governance of the transplant program would improve issues of communication and reporting. There was a general sense of the surgery component of transplantation being a technical and service contribution, with some lack of a 'team' feeling. This would require a prolonged and concerted effort to correct but is essential to a sustainable program as surgery is such a critical component. A shift to having dedicated primary renal transplant surgeons is a preferred model but will require recruitment and additional funding from the province. Recruitment of one or two dedicated transplant surgeons will require support from the vascular surgeons and urologists for donor retrieval, complex patients, as well as to maintain workloads at healthy levels.

## **H. Nephrology: Support and challenges**

The transplant program is felt to be an important component of nephrology care and an important option for the care of end stage renal failure. There was an amalgamation of clinical care with transfer of the transplant program to St. Paul's Hospital in 2001. There has been discussion within the division of nephrology for support of transplantation nephrologists, as the current system requires that two of the three nephrologists provide considerable ward and dialysis work to provide income. The discussions surrounding alternate funding had been met with some resistance by nephrology due to concerns of overall reduced income. A recent application for a Royal College of Canada training program in nephrology has been denied, with additional information being required. The lack of academic positions within nephrology and near complete use of clinical associates and community-based nephrologists was not felt to be a weakness in the application. However a full AFP with academic nephrologists and transplant nephrologists would most certainly add to any successful Royal College approved program.

The development of the transplant program in Saskatchewan is largely attributed to the efforts of Dr. Shoker, who is well recognized for his pioneering transplant efforts as well as those of the late Dr. M. Baltzan, and Dr. Barrett (Urology) who is nearing retirement. Currently, Dr. Shoker is the Medical Director of the Transplant program and the Medical Director of the Renal Transplant Program. The Program Manager is Raylene Matlock, who shares responsibility with Dr. Shoker in the Saskatoon office for the provincial program. Out of province services are independently managed by physicians for the lung, liver and heart programs. As well, there are tissue services with a Bone Bank as well as an Eye Bank. All transplant programs including non renal organs report to Dr. Shoker and Raylene Matlock. *In the organizational chart, there are no listed surgeons. Dr. Shoker reports directly to the Division of Nephrology head as well as to the Ministry Advisory Committee and the Director of Medical Operations.* There is no reporting to Surgery. Ms. Matlock reports to the Director of Renal Services and the Chronic Disease Management of the SHR. There is also a Regina office within the Saskatchewan transplant program, and a separate administrative manager (Chris Horton). The Clinical Program Manager (RM) oversees both the Saskatoon and Regina offices. The clinics in Saskatoon and Regina consist of nurse coordinators, pharmacists, social workers and transplant nephrologists. These include both assessment clinics, post-transplant follow-up clinics as well as living donor follow-up clinics.

The suspension of the transplant program was a considerable stress for the transplant nephrology group. In the absence of an immediate solution for the surgery, plans were made to transfer patients to Edmonton. Patients on the waiting list were informed officially by letter from the program. Support was provided to transport patients to Edmonton for transplantation and return to Saskatoon for post transplant follow-up, often within 10 to 14 days of transplantation. This has been also stressful of course to the transplant patients,

who often would not be from either large urban centres such as Saskatoon or Regina. Out of province travel to Edmonton from rural Saskatchewan in particular was felt to be of even greater stress than having transplantation in Saskatoon - which at least had familiarity from the transplant assessment process.

There is no formal agreement with Edmonton as to patient selection, postoperative management or immunosuppression. It was agreed that the non-sensitized patients would be suitable for transplantation in Edmonton. While this policy addressed issues of best outcomes and minimal risk, it has excluded patients that have been sensitized through transfusions, pregnancies and previous transplants and essentially has resulted in a two-tier approach to transplantation of Saskatchewan recipients. Discussions are underway to address this but solutions such as having Edmonton nephrologists conduct assessment clinics in Saskatoon would be unnecessarily complicated in this time-sensitive treatment for renal disease. High immunological risk patients may be at additional risk of graft dysfunction by shipment of organs and transfer of patients, with higher delayed graft function rates due to prolonged cold ischemic times. It was reported to the reviewers that cold ischemic times have increased from the average 12 hours to more than 20 hours as a result of patient transfers to Alberta.

*Minimized cold ischemic times should be the standard of care for high immunological risk patients and that would be best served by transplantation in Saskatoon using local donors.*

Currently, the nephrologists are following a total of 435 patients, of which 175 are living donor and 260 are deceased donor renal transplant recipients. Graft survival in the preceding five years has been quoted as being 89% for deceased donor grafts and 90% for living donor grafts, which is high and commendable if accurate. The five-year survival for living donor patients is 100% and for deceased donor patients is 87%. *There appears to be some discrepancy in the reporting of this data and may reflect the absence of a verified longitudinal transplant database.* Including Dr. Shoker, there are a total of four transplant nephrologists, who are responsible for the entire province. Dr. Shoker as Medical Director has an academic appointment, but the other nephrologists are community-based faculty, who additionally provide general nephrology service within the division of nephrology. Dr. Hassan and Dr. Mainra are well trained in transplantation medicine as well as general nephrology. Dr. Baltzan is a community-based physician who follows approximately 72 patients out of the total 435 patients in his private clinic. This has been a historic arrangement. Coverage of these patients, if required in Dr. Baltzan's absence, has been provided by the other transplant nephrologists.

*The transplant nephrologists have a central role in the transplant program. They review all patients for both living and deceased donor transplants, and it is not*

*clear that there is sufficient separation of donor and recipient assessments in the living donor program.*

The waitlist management is provided almost entirely by nephrology. All immunosuppressive protocols are generated and reviewed by nephrology. Desensitization with immune absorption or plasmapheresis is managed by the nephrologists. Participation in the living donor paired exchange program has been through Dr. Mainra who along with Dr. Shoker have good communication with the HLA laboratory. Recipient selection is based on blood group, cross match results and waiting times but also includes age, CMV status, and HLA matching. These variables are reviewed by the transplant nephrologists who apply them to the specific donor recipient matching. However, recipient selection is not based on any published and transparent algorithm and while allocation was felt to be 'fair', in the absence of a published algorithm and audits, allocation could be potentially biased. The involvement of Dr. Shoker appears to be critical in the present model, given his considerable expertise in transplantation, his knowledge of immunobiology, and his administrative roles. Surprisingly there has been little in the way of succession planning although the current transplant nephrologists have demonstrated administrative and teaching skill despite their junior appointments.

In summary the transplant nephrologists function well and are highly regarded by the transplant program members, but there are issues regarding reporting structures, co-management of the transplant program, shared development of immunosuppressive protocols and transparency of published allocation algorithms. As well, there can be improvements in the communication lines between Transplant Nephrology and other members of the transplant group. Financial support of transplant nephrologists and academic encouragement and integration into the university would be very important for a sustainable transplant program. The division of nephrology could support transplantation in the form of financial assistance and as well in independent assessment of potential living donors.

## **I. Pathology and radiology support**

Adequate pathology support is essential for a sustainable transplant program, particularly for high risk patients. The pathology support in place and historically, is substantial and the level of support exceeds most centers in Canada. Biopsy results are provided on a same-day service, and all results are reviewed with the transplant nephrologists. Additionally, special staining for antibody mediated rejection (C4d) is provided with a four hour turnaround which is excellent. Biopsies are provided by interventional radiologists again on a rapid basis. This has changed from the previous service which was primarily having urologists provide biopsies, and since 2000 biopsies are almost exclusively provided through radiology. As well radiology provides excellent support for post-transplant complications such as ureteric complications, which require nephrostomy insertion. The rate of complications requiring radiology intervention is not formally tracked, but the reviewers noted that rates may be slightly higher than expected. *Complication rates should be followed in a formal longitudinal outcome database.*

## **J. Teaching, research and academic issues**

Renal transplant physicians as well as surgeons actively participate in undergraduate and postgraduate teaching for the College of Medicine. However they are community-based faculty and teaching is remunerated on an hourly basis. Commendably Dr. Hassan has been given awards for teaching excellence. *Peer reviewed research funding is largely historic within Nephrology. There is a substantial amount of non-peer reviewed contract research and Dr. Shoker has a significant number of published research that is not related to contracts.* Dr. Shoker has a substantial research effort and is supported by largely contract research awards. He also maintains a research laboratory and currently supervises one PDF and one PhD student. The college of medicine currently supports one academic position in transplantation, namely Dr. Shoker and this comes with full financial support. As with all academic positions at the University, there is minimal accountability for that academic financial support. While the profile of transplantation at the University and within Saskatoon is high, the transplant program is not viewed to be highly academic. Firstly, any academic program requires a minimum of 5 personnel to be considered as an academic program. There are no current funds within the university to support more than the existing single academic position, but it was recognized that for a transplant program to remain viable, and sustainable, there needs to be an academic basis to the program.

The academic issues became evident through discussions with both the Dean and the department heads of Surgery and Medicine. All were enthusiastic in their support of an academic program in transplantation, but recognized the practical limitations associated with limited finances. The development of an academic



program within transplantation would benefit from a parallel and integrated development of immunology at the University, which is currently in rebuilding.

### **K. Administrative and financial support**

The current cost of the Saskatchewan program which includes Saskatoon and Regina sites, non renal organs and tissue, is approx \$2.1 million for 2010 which has not changed grossly from 2009. This persists, despite having no surgical transplant activity from July 2009. This does not include the interprovincial kidney transplant costs provided to Alberta for Saskatchewan patients and therefore, the cost per case currently is high. The administrative support and financial summaries were supplied to the reviewers. Administrative support is not a limiting issue in the program. We did not analyze the cost per case for each kidney transplant, as the funding that was listed was global for the transplant program. Cost per case will decrease with greater number of cases, and will be higher than the national average as the program restarts with additional personnel (transplant surgeons and nephrologists).

### **L. Directorship**

The medical director of the kidney transplant program is responsible for providing leadership and collaborating members of the program to ensure efficient and effective operations that meets the standards, and that the program is fiscally responsible. There were a number of items in the position description for which objective assessments of performance could be assessed. The reviewers did not seek or receive reports in support of the following requirements:

- Monitors clinical outcomes
- Ensures adherence to program-based protocols and procedures
- Ensures timely access to renal transplantation-what is the wait time to transplant.
- Ensures regular reviews of transplant protocols-are there protocols for drugs
- Reviews of budget issues
- Meets regularly with attending nephrologists and surgeons to resolve issues
- Is responsible for introducing innovations in the care of renal transplant recipients
- Promotes research
- Develops and reviews quality of care reports from the unit and compares them to national and international benchmarks
- Prepares an annual report to the clinical head of the transplant program as well the division head

- Responds to any complaints or serious adverse events
- Ensures the policies and processes are in place to ensure compliance with *Health Information Protection Act*

While many of these performance parameters were clearly achieved, some were not. It would be important that reports and reporting structures were adhered to, as communication issues will predictably emerge if not regarded. The management of a kidney transplant program extends beyond medical issues, and requires surgical input at clinical decision making and administrative levels. It was noted that there was no surgical representation on the organizational chart, nor was there a surgical input in a formalized manner on any of the parameters listed for the medical director. While recommendations here are specifically for the renal program directorship, these may similarly be relevant to the general transplant program directorship.

*Surgery should be included in a formalized responsibility for the renal transplant program. There was general agreement from almost all those interviewed that surgery should be included in a co-managed model.*

Respectfully submitted July 13<sup>th</sup>, 2010

Dr. Anthony Jevnikar



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Dr. Patrick Luke



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