Bermuda Health Council

OPINION:

ON ISLAND LIVE DONOR KIDNEY TRANSPLANTATION SERVICES

NOVEMBER 2017

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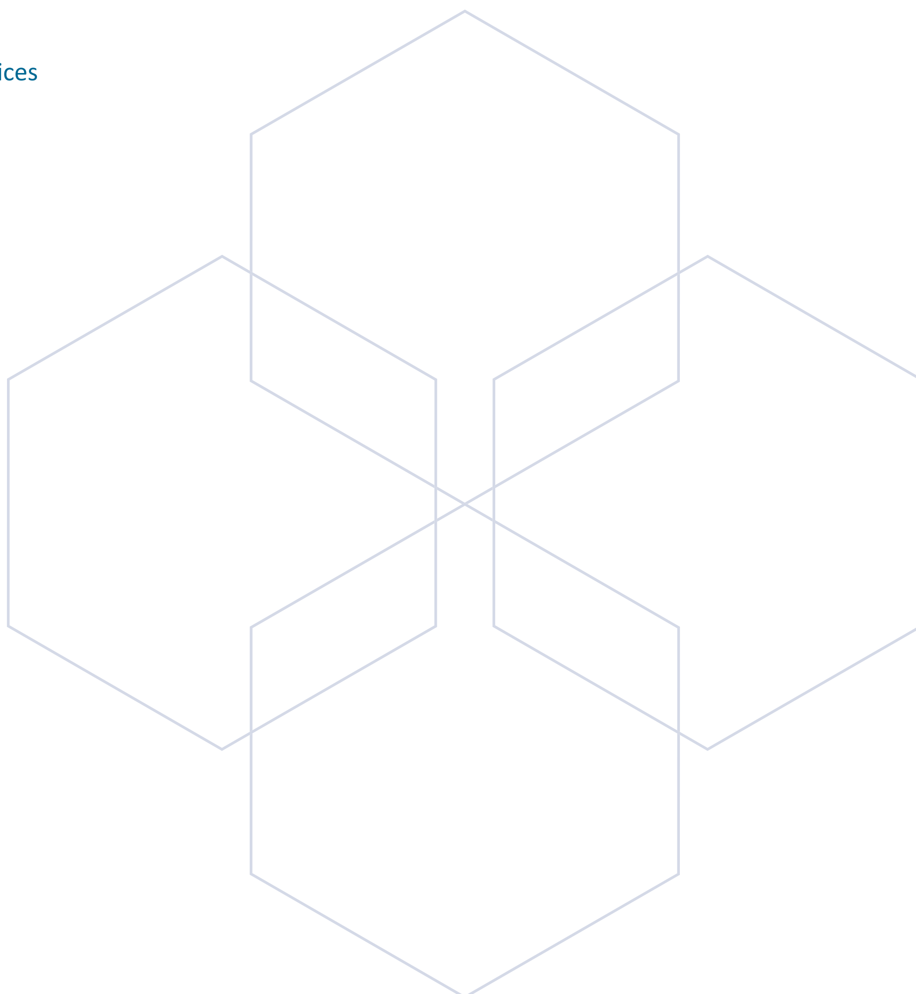

OPINION: On Island Live Donor Kidney Transplantation Services

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OPINION STATEMENT

To enable Bermuda's residents with chronic kidney disease to live healthy productive lives and to reduce healthcare costs, the Bermuda Health Council supports live donor kidney transplantation on island **only** when all of the following conditions are met:

1. Consultation with and direct involvement of local nephrologists;
2. Availability of adequately trained health professionals for pre, acute and post-operative care;
3. Evidence of cost-effectiveness both for the individual and the health system; and
4. Health system infrastructure to support transplantation including appropriate lab testing facilities, protocols for emergency transfer to overseas facilities, and mechanisms to mitigate clinical risks.

DEFINITIONS[1]

Donor: A human being, living or deceased, who is a source of cells, tissues or organs for the purpose of transplantation.

Deceased Donor: A human being declared, by established medical criteria, to be dead and from whom cells, tissues or organs were recovered for the purpose of transplantation. The possible medical criteria are:

1. Deceased Heart Beating Donor (Donor after Brain Death) - Is a donor who was declared dead and diagnosed by means of neurological criteria.
2. Deceased Non-Heart Beating Donor (Donor after Cardiac Death) = Non-heart beating donor (NHBD): - Is a donor who was declared dead and diagnosed by means of cardio-pulmonary criteria.

Living Donor: A living human being from whom cells, tissues or organs have been removed for the purpose of transplantation. A living donor has one of the following three possible relationships with the recipient:

1. Genetically Related:
    a. 1st degree genetic relative: Parent, Sibling, Offspring
    b. 2nd degree genetic relative, e.g. grandparent, grandchild, aunt, uncle, niece, nephew
    c. Other than 1st or 2nd degree genetically related, for example cousin
2. Emotionally Related: Spouse (if not genetically related); in-laws; Adopted; Friend
3. Unrelated = Non Related: Not Genetically or Emotionally Related

Transplantation: The transfer (engraftment) of human cells, tissues or organs from a donor to a recipient with the aim of restoring function(s) in the body. When transplantation is performed between different species, e.g. animal to human, it is named Xenotransplantation.

[1]All definitions have been obtained from the World Health Organization. 2009. *Global Glossary of Terms and Definitions on Donation and Transplantation.* Last accessed on 12th November 2017 at http://www.who.int/transplantation/activities/GlobalGlossaryonDonationTransplantation.pdf?ua=1

ON ISLAND LIVE DONOR KIDNEY TRANSPLANTATION SERVICES

Please note that to protect the confidence of the facility, identifying information has been altered. Generic findings which would apply to any facility are shared, except in cases where disclosure would be in the best interests of the public.

Description of Services

Proposed services would include performing liver donor kidney transplantation in the hospital setting for patients referred by local nephrologists. The treatment team would include locally trained registered health professionals and a group of physicians and surgeons with specialized training and experience in live donor kidney transplantation. Patients would receive a kidney from eligible live donors residing in Bermuda. Services would initially be delivered as part of a pilot program.

Review Process

The Health Council received a request from a government agency to opine on the merits of adding live donor kidney transplantation services to the local health system. The following process was followed:

1. The Health Council conducted a literature review and research about the safety, regulatory, and economic impact of a live donor kidney transplantation service.
2. Local and overseas claims related to live donor kidney transplantation, dialysis, and chronic kidney disease were analysed.
3. An expert advisory committee was convened comprised of persons with experience in health policy, surgery, medicine, nursing, patient advocacy, health insurance, health economics, and health regulation. Subject matter experts in nephrology also participated.
4. Deliberations included considerations of impact to patient and national health outcomes, health system capacity, community need for the service, medical and financial benefits, cost-effectiveness, hospital resources, business risks, health system infrastructure and opinions of relevant statutory bodies.

Local and Global Context

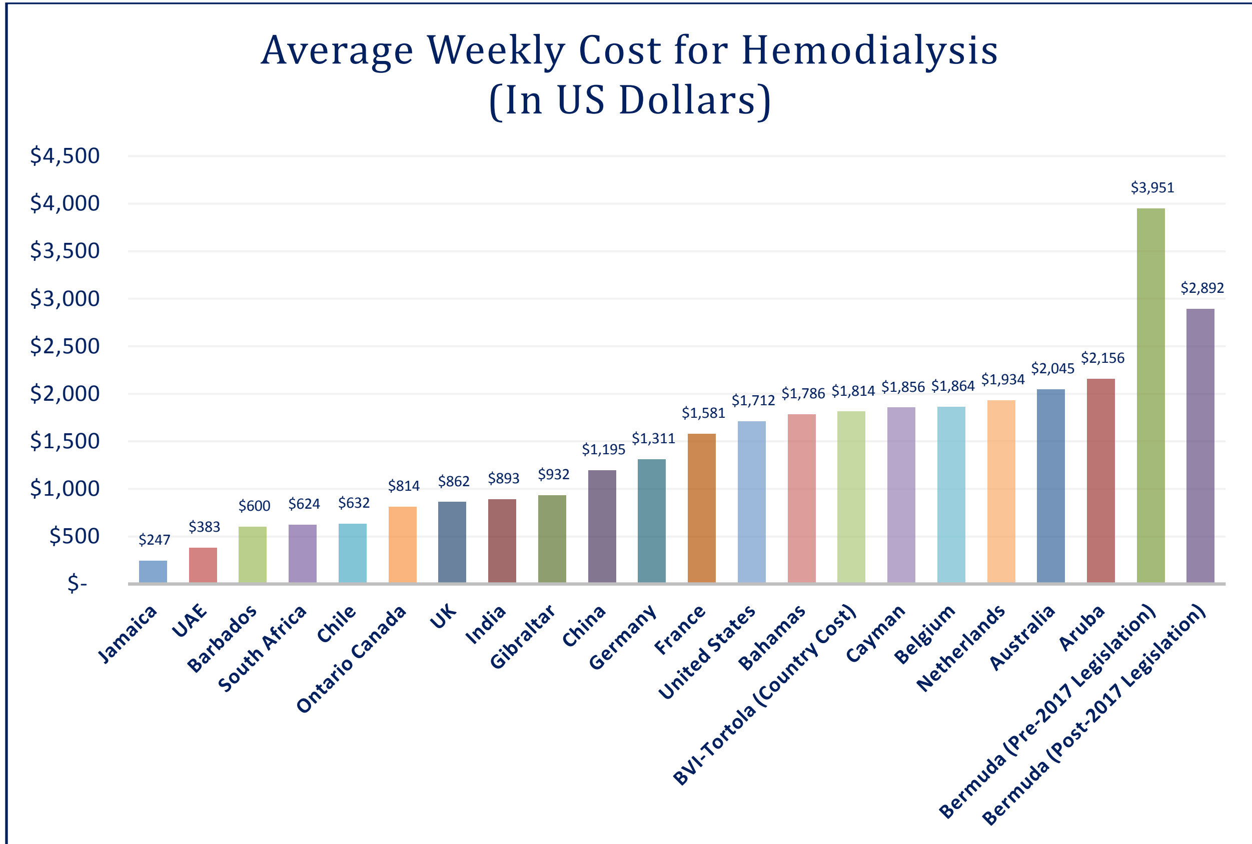
Currently, patients in Bermuda with chronic end-stage kidney disease (CKD) who require organ transplantation must travel overseas for care and often wait long periods of time for organ donations from deceased persons. Eligible Bermudian patients are placed on a transplant list in the United States through a reciprocal organ exchange agreement with Bermuda. Typically wait times can be between two and three years. Patients continue on dialysis until they are able to receive a transplant.

The insurance coverage for kidney transplants was changed on 1st June 2017 from $30,000 to $100,000. Coverage is also available for pre-surgical assessments and post-operative care. Anti-rejection drugs associated with the transplant are fully covered. Airfare, and accommodation are not usually covered. Based on 2015/16 claims data received by Bermuda Health Council from local insurers:

- There are 971 unique patients with chronic kidney disease (Prevalence)
- There are 165 unique patients receiving dialysis treatment

- The cost of related claims for chronic kidney disease as a primary diagnosis is $32,700,000
- The cost of related claims for dialysis is $24,900,000
- There are 4-5 transplants annually, most are not live donor transplants
- The costs associated with dialysis in Bermuda far exceeds other countries as per Table 1

Table 1 – Country comparison of hemodialysis costs



There are no facilities in Bermuda which currently perform any form of organ transplantation. In addition, a structured program facilitating live donors does not exist. Anecdotal evidence suggests that no local providers are considering live donor transplantation services to be performed on island at this time. There are several trained health professionals on island with experience in nephrology; experience and training in live donor kidney transplantation is limited.

Further Bermuda currently does not have the physical infrastructure, adequately trained personnel, or system capacity to perform live donor kidney transplantation. For example, some lab tests and drug levels cannot be analyzed within hospital or community labs, and there is limited capacity locally to do renal biopsies. Most importantly, trained healthcare personnel do not exist in the numbers required to support the ongoing tertiary level care in the island's acute care facility.

According to the World Health Organization, "*although end stage renal disease patients can be treated through other renal replacement therapies, kidney transplantation is generally accepted as the best treatment both for quality of life and cost effectiveness*[2]". A review of the literature reveals:

- The length of time a patient remains on dialysis influences their eligibility for a transplant
- Live donor organs are typically available sooner than deceased donor organs
- Kidneys from live donor transplantation generally last longer than those related to deceased donor transplantation; usually 10 years for a deceased donor kidney and 15-20 years for a living donor kidney [3]
- A greater chance of the donated kidney functioning immediately after transplantation, thereby greatly improving kidney transplant and patient survival

Live organ donation involves major surgery for both the recipient and the donor. These procedures pose the typical risks associated with other major surgeries. On the donor side, patients can anticipate potential recovery pains, nosocomial infections, blood clots, anesthesia associated risks, blood transfusions, surgical complications, and in rare cases death. All transplant recipients are subject to the risks above and the additional risks of organ failure and/or tissue rejection. After a kidney transplant, patients will require anti-rejection medication which can cause a variety of side effects including acne, bone thinning and damage, diabetes, excessive hair growth or loss, high blood pressure, high cholesterol, cancer risk, infections, edema, and weight gain[4].

DISCUSSION & FINDINGS

Clinical Effectiveness

1. The proposed pilot program would contribute to positive patient health outcomes including enhancing the quality and productivity of individual lives.
2. The proposed pilot program would increase health system capacity for live donor kidney transplantation benefitting the local hospital, improving local infrastructure and enabling medical travel opportunities to Bermuda for persons from other countries.
3. To enable live donor kidney transplantation, health system enhancements are required. This includes:
    - Expanding laboratory menus and decreasing testing turnaround times for tissue typing, antigen and antibody screens, viral testing, and drug levels
    - Increasing the medical specialists and surgical coverage available to ensure appropriate monitoring and continuity of care
    - Increasing pharmaceutical capacity to formulate, titrate, administer, and fine-tune the dosage of anti-rejection, antibacterial, and antiviral medications

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[2] World Health Organization. *Transplantation.* Last accessed 12th November 2017 at http://www.who.int/transplantation/organ/en/

[3] Schwarz A, Scheffner I, Chatzikyrkou C, Hermann H, and Gwinner W. *Differences between Live and Deceased-Donor Kidney Transplantation in a Centre Performing Protocol Biopsies.* American Journal of Transplant. 2013: 13 (Supplement 5). Last accessed 12th November 2017: http://atcmeetingabstracts.com/abstract/differences-between-live-and-deceased-donor-kidney-transplantation-in-a-centre-performing-protocol-biopsies/ . Information on outcomes can also be accessed on the World Health Organization website at: http://www.who.int/transplantation/gkt/statistics/kidney_outcomes/en/

[4] Kidney transplant - Risks. Mayo Clinic. 2017. Available at: http://www.mayoclinic.org/tests-procedures/kidney-transplant/details/risks/cmc-20203626. Accessed August 22, 2017.

- Enhancing availability and sophistication of KEMH surgical suites, surgical apparatus, and equipment; and increasing availability in the operating room
- Recruiting specially trained and qualified nursing, allied health, and support staff to manage both the pre-operative and post-surgical care
- Developing an emergency plan to enable overseas travel during surgery should complications arise

Patient Safety

4. There is significant risk of patient harm and high medical risks to the health system if live donor kidney transplantation were to enter the existing market; changes are required to enable safe transplantation.
5. Live donor kidney transplantation would be further complicated by:
    - The Afro-Caribbean phenotypes and antibody profiles
    - The lack of support from local specialists who would lead referrals for care
    - The reluctance of overseas facilities to accept patients transplanted outside of their facilities due to potential quality and safety concerns
    - The morbidity of the potential donor population based on prevalence of diabetes, hypertension, obesity and other chronic conditions in Bermuda
    - Poor population health which may reduce the pool of potential live donors and negatively impact the success of a live donor kidney program
6. Existing overseas facilities may offer concerns about the quality of a local transplant program; this could jeopardize future collaborative opportunities and safe transfer overseas if complications arise.
7. Investing in a local live donor kidney transplantation program may divert resources from other health system initiatives while increasing overall medical risks to patients.
8. Individual outcomes may be impacted by patient willingness to receive transplants locally, recognizing that quality improves based on the number of transplants performed.

Economic Implications

9. The expenses associated with the proposal are less cost effective than some existing options currently available to patients.
10. Local transplant patients benefit from existing affiliations with overseas specialty centers. These affiliations result in special fees for transplantation services. When compared with these special fees, the proposed fees associated with a local live donor kidney transplantation service may not be cost effective.
11. This business could positively affect patient and national health outcomes by increasing the number of transplants performed annually. The increase in number of procedures performed over time would reduce long-term costs associated with chronic kidney disease, decrease the number of people on dialysis, and reduce ancillary costs related to overseas transplantation (e.g. travel and accommodation expenses).

WHAT ARE HEALTH TECHNOLOGY REVIEWS (HTRS)?

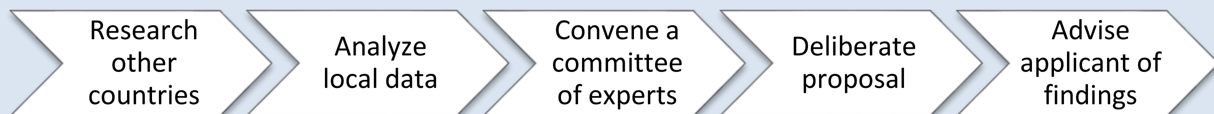
Per Section 5 (b) of the Bermuda Health Council Act 2004, the Health Council periodically reviews health services to ensure they are provided to the highest standards. This means reviewing the current services that are available, assessing future demand for services and advising about effective management and planning of services.

In early 2012, the Health Council implemented a process to systematically evaluate new services entering the health system. The process is called Health Technology Review (HTR) and has been used to evaluate the entry of 16 new health services. The reviews help health professionals, facilities, insurers, investors, government agencies and policy makers to decide which health services Bermuda should invest in, whether the health system requires these services, the financial implications of the services and highlight the patients that would benefit most.

It is within this context that the Health Council publishes this guidance. This guidance can be used by any health professional or entrepreneur seeking to establish a new service in Bermuda or revise an existing health service. It can also be used by insurers to guide reimbursement decisions. Most importantly, it can be used by the public to enhance understanding about what to expect when receiving care. Please note the guidance is not binding and is subject to change when new information becomes available or international standards change.

How does the review process work

Business owners, government departments, investors, insurers, health professionals or health facilities make a formal request for the Health Council to provide an opinion about whether a health service would be beneficial to Bermuda's health system. We review current health service utilization, unmet demand for services, population and demographic trends, health innovations, potential health policy changes, and health care delivery trends. After the request is made, here is what the Health Council does:



To ensure the integrity of the process:

1. All names are removed from the application before it is given to the committee of experts.
2. Committee members sign Confidentiality Agreements and Conflict of Interest forms.
3. The Health Council contacts regulators and agencies in other countries to obtain feedback as needed.