Trillium Gift of Life Network

Clinical Handbook for Living Kidney Donation

Version 1.0

Disclaimer: The content in this Clinical Handbook has been developed through collaborative efforts between Ontario Health, Trillium Gift of Life Network and experts from Ontario's living kidney donation programs. It is based on available literature and expert opinions at the time of development. The Clinical Handbook is not intended to be an exhaustive analysis of all kidney donation literature and practices, and may not reflect all available research and consensus from all experts. Other relevant scientific findings may have been published since completion of the Clinical Handbook and it may be superseded by an updated publication on the same topic. While every reasonable effort has been made to ensure the accuracy and validity of the information provided, TGLN and the expert contributors assume no responsibility for any errors or omissions in the content.

Ontario Health
Trillium Gift of Life Network

List of Abbreviations

CBS	Canadian Blood Services
CKD	Chronic Kidney Disease
ESKD	End-Stage Kidney Disease
KDIGO	Kidney Disease: Improving Global Outcomes
KPD	Kidney Paired Donation
MOH	Ministry of Health
OAGO	Office of the Auditor General of Ontario
OATS	Ontario Allocation and Transplantation System
ORN	Ontario Health, Ontario Renal Network
PRELOD	Program for Reimbursing Expenses of Living Organ Donors (PRELOD)
TGLN	Ontario Health, Trillium Gift of Life Network

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I. Purpose

The Clinical Handbook for Living Kidney Donation includes a clinical pathway and service bundles for kidney donation which have been developed in response to *The Office of the Auditor General of Ontario's (OAGO) 2019 Report on Chronic Kidney Disease Management* (1), and as part of the Ministry of Health's (MOH) commitment to quality healthcare and better outcomes.

It aims to identify opportunities to enhance integration of services across the living kidney donor candidate care continuum; facilitate efforts to improve existing processes within Ontario's living kidney donation programs by reducing unnecessary practice variations and optimizing resource utilization; and inform policy frameworks and implementation approaches to the care of living kidney donors in Ontario.

The Clinical Handbook will also support work by Ontario Health, Trillium Gift of Life Network (TGLN) to cost the living donor pathway as part of its review of the living-donor-transplant funding rate.

The Clinical Handbook includes the following tools to guide the development of policies, procedures, and processes:

1. A clinical pathway for typical living kidney donors from the time of referral to post-donation. The clinical pathway outlines the general process that living donor candidates in Ontario follow when moving through the donation process.
2. Services that correspond to each stage of the living kidney donation pathway.

To foster partnership and strengthen clinician engagement, the clinical pathway and service bundles were developed using opinions from clinical experts from all Ontario living kidney donor programs, guided by national and international evidence-based guidelines. As a result, the Clinical Handbook is a compendium of evidence based rationale and clinical consensus on guidelines for living kidney donors.

This document has been prepared as a tool for hospitals and individual providers to support the development of clinical patient pathways for their organizations. The clinical recommendations in this document and any subsequent adjustment to the clinical pathway and service bundles are not intended to replace the professional skill and judgement of healthcare providers, nor inhibit the development of new and innovative transplant solutions.

II. Improving Quality of Care

At the forefront of Canada's healthcare system is a commitment to provide the highest standard of hospital and healthcare services. In Ontario, the People's Health Care Act and Ontario Health's Mandate support this by creating greater public accountability, sharing clinical best practices, leveraging resources in quality improvement and digital health, as well as providing full and coordinated continuum of care through integration of legacy health agencies and other organizations across Ontario. These dimensions of quality are supported by the following six domains:

- Improve **effectiveness** and reduce variation in clinical outcomes.
- Improve **appropriateness** by reducing practice variations.
- Improve **timeliness** across the continuum of care.
- Improve **efficiency** by reducing unwarranted variation in resource utilization.
- Improve or maintain **equity** to appropriate health services.
- Improve **patient centredness** of health services.

Specific recommendations for Ontario's transplantation system were outlined in the *2010 Auditor General`s Report on Organ and Tissue Transplantation* and the *2009 Organ and Tissue Wait Times Expert Panel Report* (2,3), both of which highlighted the need for a more efficient and equitable allocation system, improved referral practices and more effective oversight for organ transplantation. While the focus of implementing these recommendations has been on developing a sustainable end-to-end transplant system, a number of initiatives have included living donor transplant recipients. For example, in response to the Auditor General Report's recommendation to undertake performance measurement and evaluation to strengthen accountability across the system, TGLN now collects patient outcome data (patient death, graft failure and graft rejection) for both deceased and living donor transplant recipients.

Furthermore, in its report, the Expert Panel specifically raised concern that Ontario does not have standard best practice guidelines for the pre- and post-care of transplant patients, stating that such guidelines are important since they would identify the care that transplant centres and the local community should provide. The Panel recommended:

- Ontario's transplantation community compile and/or develop pre- and post-transplant care best practice standards and guidelines by organ, and ensure that healthcare providers use these standards and guidelines to inform their care.
- TGLN and the transplantation community establish a system to monitor the use of best practice standards and guidelines for adult and paediatric organ transplantation, and the outcomes of these procedures.

In response, TGLN developed a Clinical Handbook for Kidney Transplantation which included a clinical pathways and corresponding services for both deceased and living donor transplant recipients.

The development of a Clinical Handbook for Living Kidney Donation complements this work, while supporting recommendations in the Auditor General's *2019 Report on Chronic Kidney Disease Management*, and aligning with the Ontario Health's Mandate and People's Health Care Act's increased emphasis on continuous quality improvement supported by evidence informed best practices and standards of care.

The clinical pathway and corresponding services set out in this Clinical Handbook and the steps taken to monitor their implementation and outcomes are intended to improve the appropriateness and efficiency of transplant care by reducing unnecessary practice variations and optimizing resource utilization, as well as enhancing integration across the living kidney donation care continuum.

Clinical Pathways and Practice Guidelines

Clinical pathways are tools used to manage quality in healthcare by standardizing processes. The objectives are to reduce unnecessary variations in practice, improve interdisciplinary cooperation, integrate care, and ultimately, improve clinical outcomes. They are especially useful in complex care systems, such as living kidney donation, where patients require a minimum set of tests and consultations to be completed. During the donor assessment process, patients are provided with kidney donor specific education and kidney specialists determine whether patients are suitable to donate. While waiting to donate, patients receive ongoing assessments by the donor program, which require blood testing and laboratory work, often from community healthcare providers. Once a living donor is matched with a recipient and deemed suitable, they are admitted and cared for by the living kidney donor program before, during, and immediately following their donor surgery. Following the procedure, donors receive follow-up care from a variety of providers including transplant specialists, nephrologists, family physicians, nurse coordinators, and other medical practitioners based on their needs. The involvement of multiple providers creates considerable opportunity for variations in practice and resource utilization as the patient moves through the pathway.

Clinical Handbooks have been developed in Ontario for kidney, liver, heart and lung transplantation. As well as supporting Ontario's review of transplant funding, the Clinical Handbooks provide a resource to facilitate efforts to improve existing processes within Ontario's transplant programs by reducing unnecessary practice variations and optimizing resource utilization.

The success of practice guidelines and clinical pathways has been documented in a variety of other areas. For example, in the treatment of community-acquired pneumonia across nineteen teaching and

community hospitals in Canada, implementation of a clinical pathway reduced the use of institutional resources without causing adverse effects on the well-being of patients (4). Other individual clinical pathways, for stroke management, inguinal hernia repair, laparoscopic surgery, pancreaticoduodenectomy, and the management of fractured femoral neck, have been shown to reduce length of stay and total costs of acute hospital admission while maintaining quality of care, improving patient outcomes, interdisciplinary co-operation and staff satisfaction (5).

A systematic review of published literature and analysis of twenty-seven studies involving 11,398 participants found that patients managed according to clinical pathways encountered a reduction in in-hospital complications as compared to usual care. Furthermore, the review presented evidence of decreased lengths of stay and reductions in hospital costs when clinical pathways were implemented (5).

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. The statements contain recommendations that are based on evidence from a rigorous systematic review and synthesis of the published medical literature. Reviews of best practice clinical guideline dissemination and implementation strategies have shown that in the majority of cases, improvements in care are observed (6). In one study of 59 clinical guidelines, the authors concluded that “guidelines improve clinical practice and achieve health gains when introduced in the context of rigorous evaluations”(7).

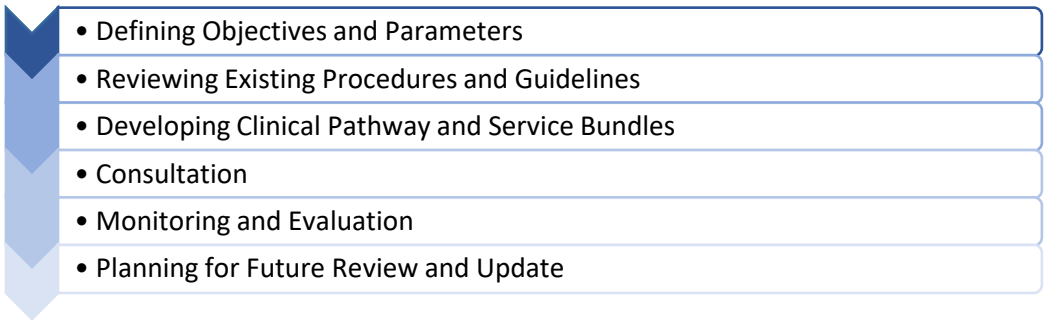
While the Clinical Handbook for Living Kidney Donation is not a clinical guideline, the clinical pathway and associated interventions set out within can improve the experience of living donors as they navigate through the donation process by facilitating integrated care plans along the continuum. With the goal of optimizing care at all stages of the patient continuum, it is intended that this Clinical Handbook will facilitate efforts to improve existing processes in the care of living kidney donors in Ontario.

III. Methods

In developing the Clinical Handbook, TGLN and the Provincial Kidney Pancreas Working Group (KPWG) took a quality-driven approach for translating evidence into action. The overarching aim was to produce a *quality-driven*, *evidence-based* clinical pathway and service bundles using an *efficient* and *transparent* methodology for *action-ready* recommendations with *multi-disciplinary applicability*:(8)

- **Quality-driven** means placing quality improvement at the forefront of clinical pathway and service bundles development, using current best evidence and multidisciplinary consensus to prioritize recommendations. Selection of key action statements is driven by opportunities to promote best practices, reduce unnecessary variations in care, and minimize inappropriate care or resource utilization.
- **Evidence-based** means supporting all decisions with the best available research evidence identified through systematic literature review and expert consensus (i.e. KDIGO, CBS, and healthcare professionals from all centres).
- **Efficient** clinical pathway and service bundles make maximum use of available resources to create a timely product, moving from conception to publication within a reasonable timeframe.
- **Transparent methodology** is explicit, reproducible, and applied consistently so guideline users can link recommendations to the corresponding level of evidence, benefit-harm-cost relationship, and the roles of values and patient preferences in decision making.
- **Action-ready** recommendations tell providers what to do, to whom, under what specific circumstance, using unambiguous language that facilitates implementation and measurement.
- **Multi-disciplinary** validity and applicability means that all stakeholders (e.g., primary care, specialists, allied health, nursing, consumers) are part of the development and implementation processes.

To achieve these goals, the following systematic process was used:



The following sections describe each of these steps in further detail.

Defining Objectives and Parameters

Objectives

In defining the objectives for developing a clinical pathway and service bundles, the KPWG was guided by the following key question:

How can Ontario's transplant system provide the best quality of care to achieve the best possible outcomes for living kidney donors?

The Working Group agreed that the Clinical Handbook was an opportunity to develop and implement best practice guidelines throughout the living kidney donor continuum, and determined that it must answer the following questions:

- **Who** should be defined as the patient population(s)?
- **What** practices and services should be employed in the treatment of living kidney donor candidates?
- **Where** can living kidney donor candidates expect to receive their treatment?
- **When** in their continuum of care can living kidney donor candidates expect to receive certain aspects of their care?

These guiding questions ensured that the potential donors' best interests remained at the centre of the development of the clinical pathway and service bundles.

Parameters

From the outset, the Working Group identified the clinical population as being all potential living kidney donors who may be eligible to donate akidney to a recipient in Ontario.

To ensure a seamless transition between different stages of the donation process, the Clinical Handbook encompasses a living donor's full continuum of care, beginning at the time of referral to a living donor program and where applicable, continuing through donation and short and long-term follow-up.

Reviewing Existing Procedures and Guidelines

The Clinical Handbook contains a set of recommended practices reviewed and agreed upon by the KPWG and through wider consultation with the donation and transplant community. In keeping with the Ontario Health's commitment to evidence-based care, considerable attention has been paid to ensure that the practices recommended here are supported by the best available evidence. A review was carried out of existing practices at each of Ontario's living kidney donor programs, as well as published national and international clinical guidelines currently utilized in the management of living kidney donors throughout the world. This involved a detailed review of the following:

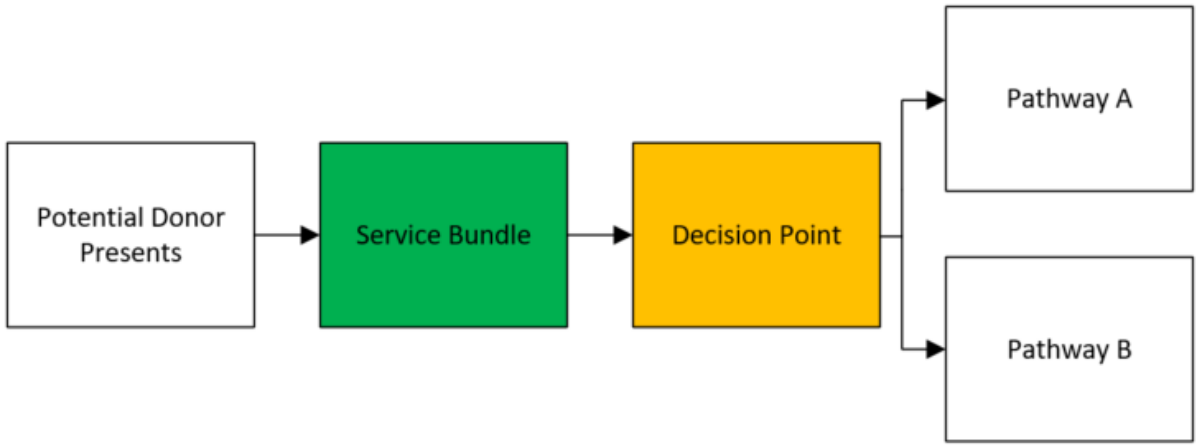
- Standard Operating Procedures from each of Ontario's living kidney donor programs
- Clinical guidelines from the following organizations:
    - KDIGO Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors (2017)
    - Canadian Society of Transplantation and Canadian Society of Nephrology Commentary on the 2017 KDIGO Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors (2020)
    - Canadian Blood Services Kidney Paired Donation Protocol for Participating Donors (2019)
    - British Transplantation Society Guidelines for Living Donor Kidney Transplantation (2018)
    - BC Clinical Guidelines for Living Donor Kidney Transplantation (2019)

The analysis was used to determine what services and procedures were carried out during a living donor's care continuum at each of Ontario's living donor programs. A full list of services was then compiled and compared with the clinical guidelines to determine if they could be considered best practice.

Developing Clinical Pathway and Service Bundles

The clinical pathway model is structured around the parameters defined for the episode of care. The model describes the pathway of each living donor candidate case, from their initial referral, through the subsequent components of care that they receive, before reaching an endpoint in their care. An exception to an endpoint of care would be in the post-donation care phase, which could continue in the community rather than the living donor program. The pathway presents the critical decision points and phases of treatment within the continuum of care. Decision points provide specific criteria for whether a particular case proceeds down one branch of the pathway or another. Once potential living donors move down a particular branch, they then receive a set of recommended practices that are clustered together as a bundle. Service bundles represent the major phases of care that living donor candidates

receive during the donation process. Figure 1 provides an illustrative example of a service bundle and assessment point:



Through the development of the clinical pathway, there are ten service bundles corresponding to the four key stages in the living kidney donation care continuum:

1. **Donor Screening and Initial Testing**
    a. **Pre-Screening:** Interventions beginning from when a potential donor contacts a living donor program, until they receive a lab requisition to begin donor work-up.
    b. **Laboratory and Diagnostic Testing:** Laboratory and diagnostic testing required for donor assessment and any other interventions beginning when a potential donor receives a lab test requisition to begin donor work-up, up to attendance at assessment appointment.
2. **Consultations and Further Donor Assessment**
    a. **Consultations:** Donor assessment consultations and donor review from assessment appointment until a potential donor is deemed suitable to proceed with living donation.
    b. **KPD Program Donors:** Additional annual work, not captured elsewhere involved in supporting the transplant from a donor enrolled in the KPD program.
    c. **ABO Incompatibility:** Additional work for ABO incompatible living donor candidates, when the recipient undergoes desensitization therapy to enable direct donation from their potential donor.
    d. **Donor Reassessment:** Repeat and/or additional donor testing if more than one year has passed since the initial donor assessment due to delays in recipient readiness for transplant.
3. **Pre-op and Peri-operative**

a. **Final Preoperative Testing:** Interventions from when booked OR is confirmed and activity immediately preceding surgery
b. **Peri-operative Phase:** Activities from day of surgery, including donation surgery, and post-operative inpatient recovery.

4. **Post-Donation After Discharge**
    a. **Year 1 Post-Donation:** Interventions following hospital discharge, including all donor follow-up provided in the first year post-donation.
    b. **Year 2+ Post-Donation:** Interventions from when a donor transitions to annual monitoring.

Services for each stage were then categorized into the following two groups:

- **Bundled services**:
  These are services that are an essential part of the living kidney donor pathway and have a standard expected duration and frequency. For these services, a minimum standard frequency for the typical living kidney donor candidate at each phase of the care continuum was assigned. For example, a serum albumin test is a bundled service that should take place one time during laboratory and diagnostic testing and annually if more than one year has passed since the initial donor assessment . It is important to note that the set frequencies do not limit every living donor's specific service needs. Although the bundles may state that living donors should have a particular test once, some may require this more often.

- **Unbundled Services:**
  These are services that can potentially be provided to living kidney donor candidates but cannot be predicted and/or assigned a standard frequency for a given patient population. Included in this group are services whose frequency varies considerably across centres or services that are required for a living donor candidate based on the physician or NP's overall assessment of their health and needs. These services should be provided at the physician or NP's discretion.

Using the expertise of Ontario clinicians, published guidelines, and available data, TGLN provided each living kidney donor program with a draft of the developed service bundles. TGLN solicited feedback from each of the programs and ensured they had an opportunity to respond to the content in the Clinical Handbook. The programs were asked the following key questions:

- Are there any services identified that should not be included in the service bundles?
- Are there any services that were not identified in the service bundles but should be included?

- How are the services outlined in the service bundles similar or dissimilar to current practice at your centre?

To ensure transparency in the consultation process, feedback was shared with each of the living donor programs detailing the action taken on proposed changes to the service bundles. Centres were then given an opportunity for final review of the revised bundles and asked to submit any final comments.

Monitoring and Evaluation

Efforts to regularly monitor and evaluate the kidney transplantation system in Ontario are taken to improve the transplant process and identify opportunities for further improvement. With the expertise of the Provincial Working Groups, TGLN will identify key performance indicators for the living kidney donor pathway that will help clinicians and administrators monitor the implementation of the Clinical Handbook.

As part of TGLN's quality improvement framework, applicable performance indicators will be reported and distributed to living donor programs. Living kidney donor programs may use the reports to evaluate their own processes at each stage of the care continuum and enable centres to track, audit, and evaluate the implementation of the clinical pathway and best practice services within their centres. Through such monitoring, variances can be identified, progress monitored, and practices refined over time to improve patient outcomes.

TGLN, in collaboration with the Kidney Pancreas Working Group will utilize performance indicators to monitor and evaluate the transplantation system as a whole. The Group may review the current state of the system and make recommendations to support practice changes where notable variations have been identified. Indicators will be reviewed regularly to ensure they remain relevant and align with quality objectives to promote ongoing improvement at both hospital and system levels.

Plan for Future Review and Update

The clinical pathway and service bundles will be revised when appropriate to ensure developments in living kidney donation best practice are reflected. Upon the release of new or updated clinical practice guidelines, new evidence, or policy changes TGLN will conduct a review of the Clinical Handbook. If no guidelines are published, the Clinical Handbook will be reviewed every 4 years by the KPWG. Comments received will be incorporated and reviewed by the Working Group as necessary.

IV. Overview of Living Kidney Donation

Kidney disease describes a variety of diseases and disorders that affect the kidneys. Most diseases of the kidney attack its filtering units, the nephrons, and damage the kidney's ability to eliminate wastes and excess fluids. Chronic renal failure, or chronic kidney disease (CKD), is a slow and progressive decline of kidney function, most commonly caused in North America by diabetes or high blood pressure. While not all CKD patients progress to end-stage kidney disease (ESKD), for those who do, dialysis or kidney transplantation is required to sustain life.

Up to 1 in 10 Canadians have some form of kidney disease (10). According to the Canadian Institute for Health Information, there were 42,000 people being treated for ESKD in 2020, of whom 24,000 were receiving dialysis and 18,000 were living with a functioning kidney transplant. The number of Canadians receiving chronic dialysis has nearly doubled in the past 20 years (11).

Kidney transplantation is the best treatment available for most patients with end-stage kidney disease (12). It not only improves the quality of life for patients, but has shown to be a life-prolonging procedure. Unfortunately, many patients who would benefit from a kidney transplant do not receive one. The number of people in need of a transplant continues to rise, and there are too few kidneys available from deceased donors to meet the demand (13). The alternative, a transplanted kidney from a living donor offers many advantages that include a longer duration of patient and graft survival, and shorter wait times to receive a kidney. The average wait time from starting dialysis to receiving a deceased donor transplant is approximately 4 years, compared to less than 1 year for patients who receive a kidney from a living donor (11). Averting years and in some cases any time on dialysis is not only beneficial to patients but results in substantial healthcare savings.

Living kidney donation, however, requires that healthy individuals voluntary undergo major surgery with no physical benefit to themselves. Someone who becomes a living donor (and to a lesser extent a person who is evaluated as a living donor) is accepting some degree of personal risk that they would not otherwise incur. Diverse issues may arise during evaluation and candidates may have negative psychosocial consequences if they are deemed ineligible to donate. There are short term risks associated with the surgery and donors face restricted duties for 6 weeks while recovering from surgery (14). Long-term medical outcomes include a higher risk of ESKD, cardiovascular disease, and all-cause mortality compared with non-donors who would have been eligible for donation (15).

While most potential living donors are willing to accept a degree of risk, such risks reinforce the need for careful selection of potential donors and rigorous processes to minimize adverse outcomes.

V. Living Kidney Donation in Ontario

Volumes

Over the past five years over 1000 living donor kidney transplantations have been performed in Ontario. There are seven centres at which living kidney donor transplant procedures are performed. There are six adult programs: University Health Network, St. Michael's Hospital, St. Joseph's Healthcare Hamilton, London Health Sciences Centre, The Ottawa Hospital and Kingston General Hospital. The paediatric kidney transplant program is located at the Hospital for Sick Children, in addition to London Health Sciences Centre performing paediatric kidney transplantations.

Table 1 shows the number of living kidney donor transplants that have been completed in Ontario since 2017.

Table 1: Living Kidney Donor transplantation, 2017-2021					
	2017	**2018**	**2019**	**2020**	**2021**
Transplants	213	219	242	171	241

Source: TGLN, 2022

Ontario Health, Trillium Gift of Life Network

Ontario Health, Trillium Gift of Life Network is an agency of the Ontario Ministry of Health with the responsibility for co-ordinating the donation of organs and tissue in Ontario. Its mandate was extended to include transplantation in 2011/12 following recommendations from the *2010 Auditor General`s Report on Organ and Tissue Transplantation* and the *2009 Organ and Tissue Wait Times Expert Panel Report* for an integrated donor and transplant system.

TGLN's transplant strategy aims to support the development of a sustainable end to end transplant system and to continually strive to improve the dimensions of quality, safety, effectiveness, access, patient centred care – all to enable better patient outcomes. This includes developing a provincial transplant system that provides equitable access through standardized processes and planning to enable better patient outcomes, and harmonizing the patient journey across the transplant continuum from pre-transplant through to post-transplant care.

In conjunction with this work, TGLN is committed to enhancing the living donor system in Ontario, by promoting living kidney donation, bringing about standardization of donation practices and enhancing the living donor experience. This work is supported by TGLN through the Provincial Kidney Pancreas Working Group, which includes medical and administrative membership from each of Ontario's kidney

transplant programs. In addition, TGLN works closely with Ontario Health, Ontario Renal Network (ORN), Canadian Blood Services and each of Ontario's living kidney donor programs.

The following initiatives have been implemented in Ontario aimed at improving patient access and equity, and the quality of care along the patient continuum:

- **Kidney Paired Donation**
  Kidney paired donation (KPD) is a program that matches transplant candidates with suitable living donors. It gives recipients a chance to receive a living donor kidney transplant, even if they are not a direct match with their living donor. Canada's KPD program is run by Canadian Blood Services, working with the living kidney donation and kidney transplant programs across the country. List exchange or anonymous donors who do not want to participate in KPD can donate to an Ontario waitlist recipient. A list exchange living donor is a person who gives one of their kidneys to a person on the waiting list. In exchange, the intended recipient is given priority status on the deceased donor transplant list.

- **Access to Kidney Transplantation and Living Donation (AKT) Strategy**
  In 2015, the ORN and TGLN partnered to develop the AKT Strategy with the aim of enhancing access and improving patient' experiences with transplantation, with a focus on living kidney donation. The Strategy is centred around four pillars: Quality Improvement, Transplant Ambassador Program, Education and Data. Taking a clustered randomized trial approach, phase 1 was implemented with 13 Regional Renal Programs (RRPs). The Strategy was expanded to all 27 RRPs in January 2022 with the goal of increasing living kidney donor transplant in Ontario to 300 per year by 2025.

- **Organ Allocation and Transplant System (OATS)**
  TGLN is in the process of implementing a new organ allocation system. The new system will have enhanced capabilities around living donation such as easier donor to recipient matching and improved living donor data.

- **Program for Reimbursing Expenses of Living Organ Donors (PRELOD)**
  PRELOD is a program administered on behalf of the Ministry of Health to reimburse living donors for expenses related to the donation process for those donating to an Ontario recipient. Expenses eligible for reimbursement for include travel, accommodations, meals, and loss of income. The program was reviewed in 2020 and underwent significant enhancements to increase reimbursement amounts, broaden eligibility criteria and improve the application process.

The development of the Clinical Handbook is part of the ongoing provincial initiative to facilitate Ontario's goals of consistently delivering high quality living kidney donor care across the province.

VI. Clinical Pathway for Living Kidney Donation

The clinical pathway outlines the process that the typical living donor donating in Ontario can expect when moving through the living kidney donation process. It is categorized into the following four key stages of the living donation care continuum:

Donor Screening and Initial Testing

- **Pre-Screening:** Interventions beginning from when a potential donor contacts a living donor program, until they receive a lab requisition to begin donor work-up.
- **Laboratory and Diagnostic Testing:** Laboratory and diagnostic testing required for donor assessment and any other interventions beginning when a potential donor receives a lab test requisition to begin donor work-up, up to attendance at assessment appointment.

Consultations and Further Donor Assessment

- **Consultations:** Donor assessment consultations and donor review from assessment appointment until a potential donor is deemed suitable to proceed with living donation.
- **KDP Program Donors:** Additional annual work, not capture elsewhere involved in supporting the transplant from a donor enrolled in the KDP program
- **ABO Incompatibility:** Additional work for ABO incompatible living donor candidates, when the recipient undergoes desensitization therapy to enable direct donation from their potential donor.
- **Donor Reassessment:** Repeat and/or additional donor testing if more than one year has passed since the initial donor assessment due to delays in recipient readiness for transplant.

Pre-op and Peri-operative

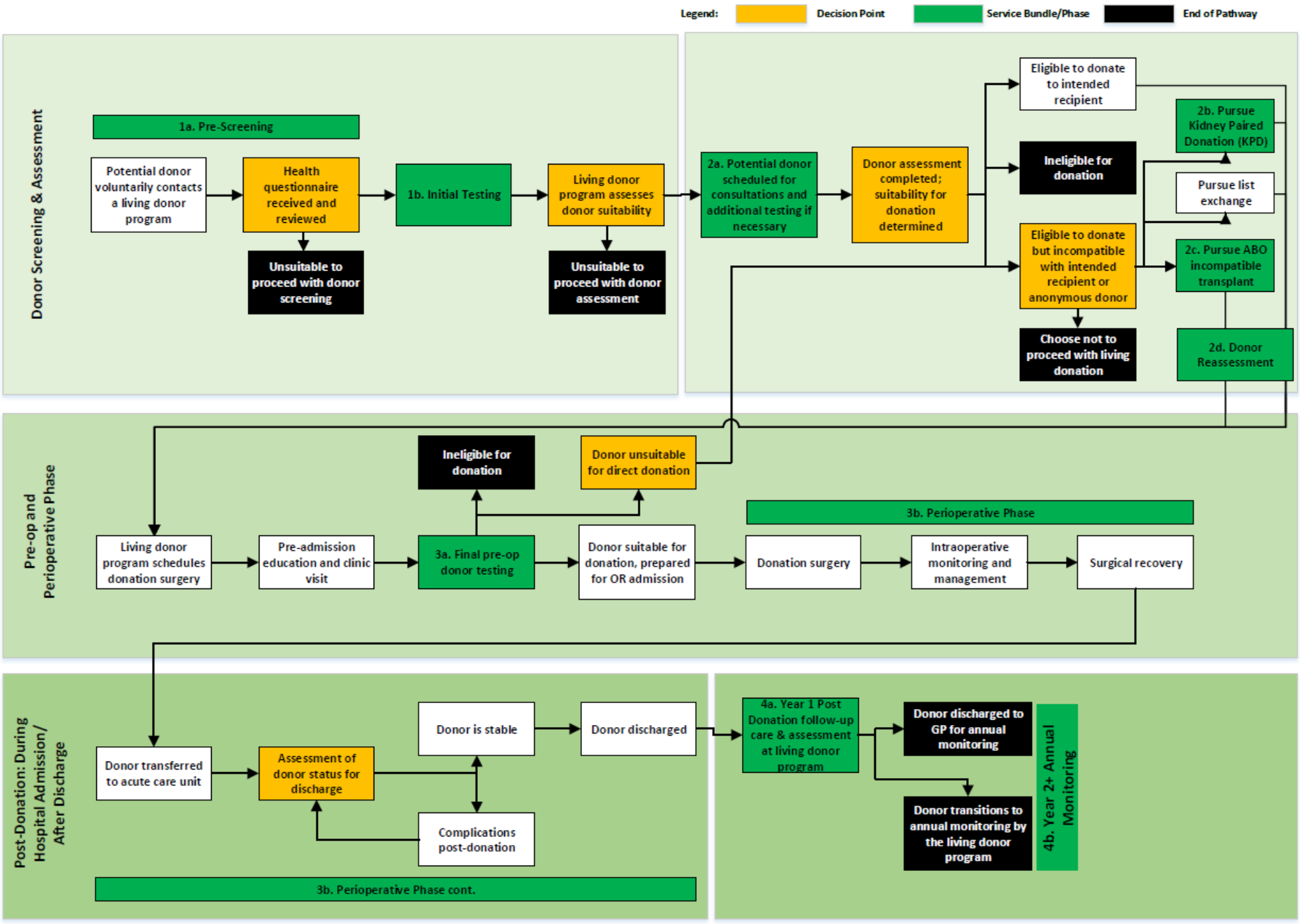
- **Final Pre-operative Testing:** Interventions from when booked OR is confirmed and activity immediately preceding surgery
- **Peri-operative Phase:** Activities from day of surgery, including donation surgery, and post-operative inpatient recovery.

Post Donation After Discharge

- **Year 1 Post-Donation:** Interventions following hospital discharge, including all donor follow-up provided in the first year post-donation.
- **Year 2+ Post-Donation:** Interventions from when a donor transitions to annual monitoring.

The pathway is intended to be a general guide to the living donation process and identify what donor candidates can expect during the specific time periods. It presents decision points and phases of treatment (service bundles) within an episode of care. The list of services for each service bundle are detailed in section VII.

The clinical pathway and service bundles should be used in tandem to guide the care of living kidney donors in Ontario.



Note: Potential donors can choose to terminate the assessment process at any time before donation surgery

VII. Service Bundles

The Service Bundles outline the full scope of services and the frequencies with which they may be provided to the typical living kidney donor candidates at each stage of their donor assessment. The timing of when these services should be administered during the care continuum is indicated in the Clinical Pathway. Although all services will be provided as part of the living donor process, not all will be carried out at the living donor program.

Unbundled services, which refer to services which cannot be predicted and/or do not have a standard frequency for a given patient population are not listed.

The Services Bundles do not replace the professional skill and judgement of healthcare providers, but rather ensure minimum standards of care are met for all patients regardless of where care is being provided. They cannot be used to apply to all patients in all circumstances and cannot be used as a legal resource.

Phase 1. Donor Screening and Initial Testing

1a. Pre-Screening

Donor Review	
Patient Enquiries/Education	1-2 times (Up to total of 60 minutes)
Communication with patient about submitted applications	1-2 times (Up to total of 60 minutes)
Living Donor Coordinator Donor Application Review	Once (Up to total of 30 minutes)
Nephrologist Review	As needed (Up to total of 15 minutes)
Case Coordination Meeting	As needed (Up to total of 15 minutes)

1b. Laboratory and Diagnostic Testing

Donor Review			
Patient Education		1 to 3 times (up to total of 120 minutes)	
Regional Renal Program Communication re tx recipient		Once (up to total of 10 minutes)	
Living Donor Coordinator Patient Contact		1-3 times (up to total of 60 minutes)	
Living Donor Coordinator Chart Prep		1-3 times (up to total of 60 minutes)	
MD or NP Review		Once (up to total of 30 minutes)	
Case Coordination Meeting		Once (up to total of 15 minutes)	
Lab Testing			
Sodium	Once	A1C	Once
Potassium	Once	Fasting lipid profile	Once
Chloride	Once	PTH	As needed
Bicarbonate	Once	Total Protein	Once
Calcium	Once	Oral Glucose Tolerance Test (OGTT)	Once
Phosphate	Once	GGT	Once
ALP	Once	CBC	Once
Urea	Once	INR/PTT	Once
Urate	Once	ACR	Twice
Albumin	Once	24-hour urine (including creatinine	Once then as
AST or ALT	Once	clearance, proteinuria and albuminuria	needed
Bilirubin	Once	measurements)	
Creatinine/eGFR	Twice	Midstream urine for culture	Once
FBG	Twice	Urinalysis	Twice then as needed

Infections Disease Screening			
HIV	Once	HCV	Once
HTLV-I	Once	CMV	Once
HTLV-II	Once	EBV	Once
HBsAg	Once	Syphilis	Once
HBcAb	Once	West Nile Virus	Once
Hep B Ab	Once	TB skin test	Once
Histocompatibility			
Blood Group	Twice		
HLA typing	Once		
Imaging			
Chest X-ray	Once	Renal Scan	Once
Abdominal CT angiogram	Once	US of abd/pelvis	Once
Cancer Screening			
Breast	Once	Colon cancer (FIT)	Once
Cervical	Once	Colon cancer (colonoscopy)	As needed
Prostate	Once		
Cardiac			
Echocardiogram	Once	Stress test	Once
EKG	Once		
Other			
Height	Once	Blood pressure (office based)	Twice
Weight	Once	24-hour ambulatory blood pressure	Once
Waist circumference	Once	Pulmonary function test	As needed
Calculated BMI	Once	Physical examination	Once
Beta HCG	Once	Flow Cross Match	Once
Creatinine clearance (DPTA scan)	Once	Virtual Cross Match	Once
Medical-Social History Questionnaire	Once		

Phase 2. Consultations and Further Donor Assessment

2a. Consultations

Donor Review	
Patient Education	1-4 times (up to a total of 60 minutes)
Regional Renal Program Communication re tx recipient	Once (up to total of 10 minutes)
Living Donor Coordinator Patient Contact	2-4 times (up to a total of 90 minutes)
Living Donor Coordinator Chart Prep	1-4 times (up to a total of 60 minutes)
MD or NP Review	1-3 time (up to a total of 60 minutes)
Surgeon Review	Once (up to a total of 30 minutes)
Case Coordination Meeting	1-3 times (up to a total of 30 minutes)
Consultations	
Psychiatry	Once (up to a total of 60 minutes)
Social Work	Once (up to a total of 90 minutes)
Transplant Coordinator	Once (up to a total of 90 minutes)
Nephrologist	Once (up to a total of 90 minutes)
Surgeon	Once (up to a total of 60 minutes)
Other allied health professionals (e.g. Cardiology, Respirology, Haematology etc.	As needed

2b. KPD Program Donors (if applicable)

Living Donor Coordinator Support	
Communication with CBS	Ongoing (up to a total of 60 minutes)
Communication with other living donor transplant programs	Ongoing (up to a total of 120 minutes)
Communication with patient specific to KPD	Ongoing (up to a total of 90 minutes)
Communication with HLA lab	3-5 times (up to a total of 30 minutes)
Chart data entry	1-3 times (up to a total of 45 minutes)
Shipping and receiving coordination	Ongoing (up to a total of 8 hours)
Post-op admin follow-up	1-2 times (up to a total of 30 minutes)
Donor Review	
Transplant Coordinator Review	1 to 3 times (up to total of 120 minutes)
Nephrologist Review	2-3 times (up to a total of 120 minutes)
Surgeon Review	1-2 times (up to a total of 60 minutes)
Case Coordination Meeting	1-2 times (up to a total of 60 minutes)
Histocompatibility	
Additional HLA Crossmatch	2 times

2c. ABO Incompatibility (if applicable)			
Consultations			
Donor Education		Once (up to a total of 30 minutes)	
Lab Testing			
Subgroup if blood group A	1-2 times		

2d. Donor Reassessment			
Donor Review			
Living Donor Coordinator Patient Contact		1-2 times (up to a total of 60 minutes)	
Living Donor Coordinator Chart Prep		1-2 times (up to a total of 20 minutes)	
MD/NP Review		1-2 times (up to a total of 30 minutes)	
Surgeon Review		As needed (up to total of 10 minutes)	
Case Coordination Meeting		As needed (up to total of 10 minutes)	
Consultations			
Education		As needed (up to a total of 60 minutes)	
Nephrologist		Once as needed (up to a total of 60 minutes)	
Social work		Once as needed (up to a total of 60 minutes)	
Other allied health professionals		As needed	
Lab Testing			
Sodium	Once	FBG	Once
Potassium	Once	A1C	Once
Chloride	Once	Fasting lipid profile	Once
Bicarbonate	Once	Total protein	Once
Calcium	Once	Oral Glucose Tolerance Test	As needed
Phosphate	Once	GGT	Once
ALP	Once	CBC	Once
Urea	Once	INR/PTT	Once
Urate	Once	ACR	Once
Albumin	Once	24-hour urine	Once
AST or ALT	Once	Urinalysis	Once
Bilirubin	Once	Urine culture	Once
Creatinine/ eGFR	Once		
Infectious Disease Screening			
HIV	Once	CMV	Once
HTLV-I	Once	EBV	Once
HTLV-II	Once	Syphilis	Once
HBsAg	Once	West Nile Virus	Once
HBcAb	Once	TB skin test	Once
HCV	Once		

Histocompatibility			
HLA crossmatch	once		
Imaging			
Chest x-ray	Once	Renal ultrasound	Once
Cardiac			
Echocardiogram	As needed	Stress test	As needed
Other			
Height	Once	Beta HCG	Once
Weight	Once	PAP	Once
Waist circumference	Once	PSA	Once
Calculated BMI	Once	FIT	Once
Blood pressure	Once	Medical-Social History Questionnaire	Once
Physical examination	Once		

Phase 3. Pre-Op and Peri-operative

3a. Pre-operative Donor Testing

Donor Review			
Living Donor Coordinator Patient Contact		2-5 times (up to a total of 60 minutes)	
Living Donor Coordinator Chart Prep		2-5 times (up to a total of 120 minutes)	
MD/NP Review		1-4 times (up to a total of 60 minutes)	
Surgeon Review		1-2 times (up to a total of 60 minutes)	
Consultations			
Education		1-2 times (up to a total of 60 minutes)	
Nephrologist		Once (up to a total of 30 minutes)	
Surgeon		Once (up to a total of 30 minutes)	
Social Work		Once (up to a total of 30 minutes)	
Anesthesia		Once (up to a total of 60 minutes)	
Other allied health professionals		As needed	
Lab Testing			
Sodium	Once	AST or ALT	Once
Potassium	Once	Bilirubin	Once
Chloride	Once	Creatinine	Once
Bicarbonate	Once	FBG	Once
Calcium	Once	Total Protein	Once
Phosphate	Once	CBC	Once
ALP	Once	INR/PTT	Once
Urea	Once	ACR	Once
Urate	Once	Urine culture	Once
Albumin	Once		
Infectious Disease Screening			
HIV	Once	CMV	Once
HTLV-I	Once	EBV	Once
HTLV-II	Once	Syphilis	Once
HBsAg	Once	West Nile Virus	Once
HBcAb	Once	COVID screening questionnaire	Once
HCV	Once	NAT testing if positive Hep B, C, or HIV	As needed
Histocompatibility			
Blood group	Once	HLA Crossmatch	Once
Cardiac			
ECG	Once		

Other	
30-day Medical and Social History Questionnaire	Once
3b. Peri-operative Phase	
Consultations	
Surgeon	As needed (up to a total of 45 minutes)
Anesthesia/Pre-Operative Medicine	As needed (up to a total of 45 minutes)
Other	
COVID-19 test	Once, then as needed
Donation Surgery	
Pre-Operative Assessment	
Surgery including transplant surgeon, surgical team, anesthesiologist, operating room staff, and all other resources required during the surgery.	
Immediate Post-Donation Monitoring and Evaluation	
Post-Anesthetic Care (recovery phase)	
Post-Operative Care Unit	
Diagnostic and Laboratory Assessment	

Phase 4. Post-Donation

4a. Year 1 Post-Donation

Donor Review			
Living Donor Coordinator Patient Contact		1-2 times (up to a total of 60 minutes)	
Living Donor Coordinator Chart Prep		1-2 times (up to a total of 60 minutes)	
MD/NP Review		1-2 times (up to a total of 30 minutes)	
Surgeon Review		Once (up to a total of 15 minutes)	
Consultations			
Nephrology & NP		2 times (up to a total of 60 minutes)	
Living Donor Coordinator		1-3 times (up to a total of 60 minutes)	
Surgeon		Once (up to a total of 30 minutes)	
Other allied health professionals (please specify):		As needed	
Lab Work			
Hemoglobin	2 times	CBC	Once
Electrolytes	2-3 times	Urinalysis	1-2 times
Glucose	1-2 times	Urine ACR	1-3 times
Creatinine	1-2 times	Urine PCR	Once
Lipids	Once	24-hour clearance	Once
A1C	Once	Microscopic Urinalysis	1-3 times
Other			
Blood pressure	1-2 times	Physical examination	Once
BMI	1-2 times		

4b. 2+ Post-Donation

Donor Review			
Living Donor Coordinator Patient Contact		Once (up to a total of 30 minutes)	
Living Donor Coordinator Chart Prep		Once (up to a total of 30 minutes)	
MD/NP Review		As needed	
Consultations			
Nephrology or NP		Once (up to a total of 30 minutes)	
Lab Work			
Hemoglobin	Once	Lipids	Once
Electrolytes	Once	CBC	Once
Glucose	Once	Urinalysis	Once
Creatinine	Once	Urine ACR	Once
A1C	Once	24-hour clearance	Once
Lipids	Once		
Other			
Blood pressure	Once	Physical examination	Once
BMI	Once		

VIII. Implementation

The Clinical Handbook is a compendium of evidence-based and clinical consensus guidelines created with the goal of improving quality of living kidney donor care delivery and outcomes as measured through performance indicators. This toolkit is not intended to replace the professional skill and judgement of healthcare providers, nor inhibit the development of new and innovative transplant solutions.

Successful implementation of the Clinical Handbook can be facilitated by leveraging the following components:

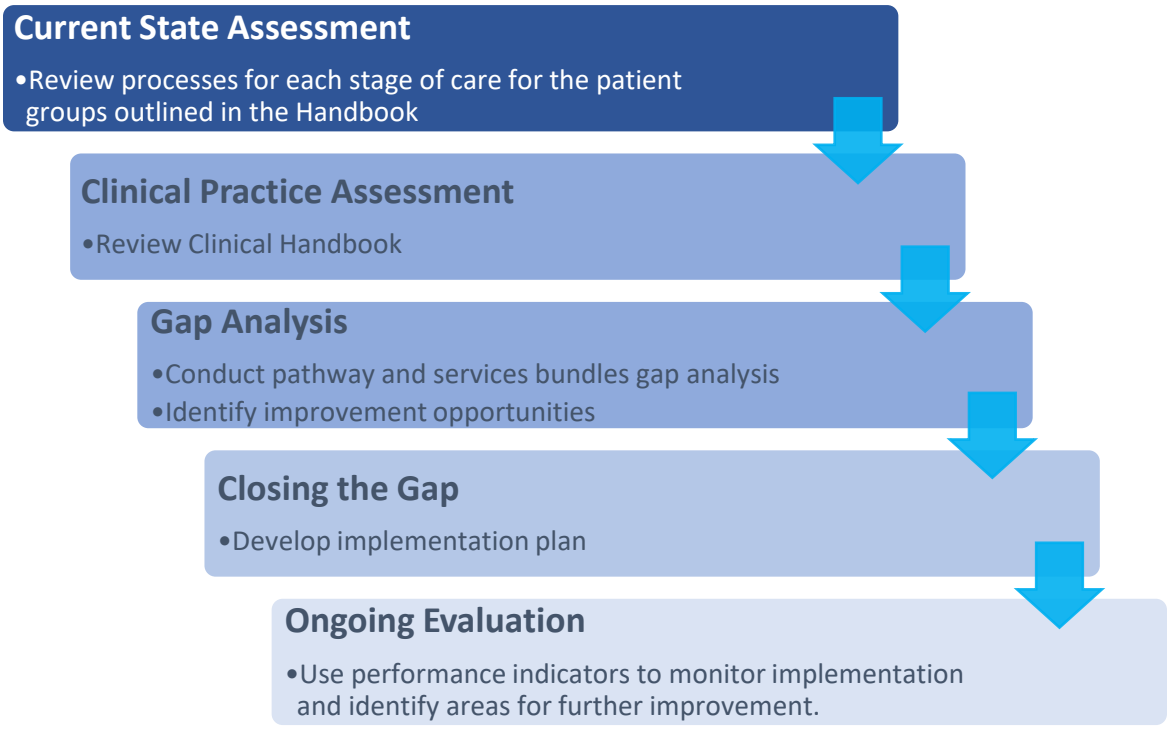
- **Building a shared vision for clinical practice:** The Clinical Handbook is an opportunity to share clinical consensus guidelines that will allow the system to provide even better quality care, while increasing system efficiencies.

- **Engaging leadership for change:** Senior leaders can support the vision for change by providing a clear message about the implications of guideline implementation.

- **Supporting clinical engagement:** From the outset, staff, physicians and other clinicians should be provided with sufficient information that will help them understand the importance of this initiative, including its impact on patient care.

To achieve a shared vision for clinical practice, living kidney donor programs are encouraged to review their current processes in relation to the clinical pathway and identify any variation that exists. As living kidney donation is a complex system, when a variation is identified, programs are encouraged to work within their centres to understand the variation in developing their local clinical pathway. To help with the review process the following roadmap to implementation has been suggested.

Roadmap to Living Kidney Donation Clinical Pathway and Service Bundles Implementation



The Clinical Handbook provides an opportunity to build a shared vision for clinical practice for living kidney donation to improve quality of care, while maximizing the effective use of available resources. The Kidney Pancreas Working Group will support and monitor this work. The Clinical Handbook will be reviewed regularly by the Working Group and when appropriate, updated with new recommended practices, evidence, and policy changes.

IX. References

1. The Office of the Auditor General of Ontario's (OAGO) Report on Chronic Kidney Disease Management. 2019

3. The Office of the Auditor General of Ontario's (OAGO) Teport on Organ and Tissue Donation and Transplantation. 2010

4. Report of the Organ and Tissue Transplantation Wait Times Expert Panel. 2009.

5. Marrie TJ, Lau CY, Wheeler SL, Wong CJ, Vandervoort MK, Feagan BG. A controlled trial of a critical pathway for treatment of community-acquired pneumonia. CAPITAL Study Investigators. Community-Acquired Pneumonia Intervention Trial Assessing Levofloxacin. JAMA. 2000 Feb 9;283(6):749–55.

6. Rotter T, Kinsman L, James E, Machotta A, Gothe H, Willis J, et al. Clinical pathways: effects on professional practice, patient outcomes, length of stay and hospital costs. Cochrane database Syst Rev. 2010 Jan;(3):CD006632.

7. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess. 2004 Feb;8(6):iii – iv, 1–72.

8. Grimshaw JM, Russell IT. Achieving health gain through clinical guidelines II: Ensuring guidelines change medical practice. Qual Health Care. 1994 Mar;3(1):45–52.

9. Rosenfeld RM, Shiffman RN. Clinical practice guideline development manual: a quality-driven approach for translating evidence into action. Otolaryngol Head Neck Surg. 2009 Jun;140(6 Suppl 1):S1–43.

10. The Kidney Foundation of Canada [Internet]. Available from: www.kidney.ca

11. Canadina Institute for Health Information. Organ Replacement in Canada: CORR Annual Statistics [Internet]. Availabe from www.cihi.ca

12. UK Renal Association. Assessment of the Potential Kidney Transplant Recipient [Internet]. 2010 Available from: www.renal.org

13. Getchell L, McKenzie S, Sontrop J, Hayward J, McCallum M and Garg A. Increasing the Rate of Licing Donor Kidney Transplatation in Ontario: Donor- and Recipient-Identified Barriers and Solutions. Canadian Journal of Kidney Health and Disease 2017;4:1–8

14. Garg A. Helping More Patients Receive a Living Donor Kidney Transplant. Clin J Am Soc Nephrol 13: 1918-1923, 2018

15. Mjoen G, Hallan S, Hartmann A, Foss A et al. Kidney International 2014 86, 162-167

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