

# A Comprehensive Quality Assurance Platform in Canada for National Point-of-Care Chronic Kidney Disease Screening: The Kidney Check Program



Sarah Curtis<sup>1</sup>, AbdulRazaq Sokoro<sup>3,4,5</sup>, Heather Martin<sup>1</sup>, Lorraine McLeod<sup>7,9</sup>, Caroline Chartrand<sup>9</sup>, Barry Lavallee<sup>9</sup>, Cathy Woods<sup>6</sup>, Michelle Di Nella<sup>1</sup>, Adeera Levin<sup>6,8</sup> and Paul Komenda<sup>1,2,6</sup>

<sup>1</sup>Chronic Disease Innovation Centre, Seven Oaks Hospital, Winnipeg, MB, Canada; <sup>2</sup>Max Rady Department of Medicine and Community Health Sciences, University of Manitoba, Winnipeg, MB, Canada; <sup>3</sup>University of Manitoba, Faculty of Health Sciences, Department of Pathology, Winnipeg, MB, Canada; <sup>4</sup>Department of Internal Medicine, University of Manitoba, Winnipeg, MB, Canada; <sup>5</sup>Shared Health, Diagnostic Services, Winnipeg, MB, Canada; <sup>6</sup>CanSOLVE CKD Network, Vancouver, BC, Canada; <sup>7</sup>First Nations Health and Social Secretariat of Manitoba, MB, Canada; <sup>8</sup>The University of British Columbia, Vancouver, BC, Canada; and <sup>9</sup>Diabetes Integration Project, Winnipeg, MB, Canada

**Correspondence:** Paul Komenda, Chronic Disease Innovation Centre, Seven Oaks Hospital, 2300 McPhillips St., Winnipeg, MB, Canada, R2V 3M3. E-mail: [paulkomenda@yahoo.com](mailto:paulkomenda@yahoo.com)

Received 29 September 2020; revised 12 November 2020; accepted 17 November 2020

*Kidney Int Rep* (2021) 6, 513–517; <https://doi.org/10.1016/j.ekir.2020.11.031>

© 2020 International Society of Nephrology. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

**KEYWORDS:** chronic kidney disease (CKD); patient-oriented research; patient-engagement; patient-centered care; point-of-care testing; screening

© 2020 International Society of Nephrology. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## INTRODUCTION

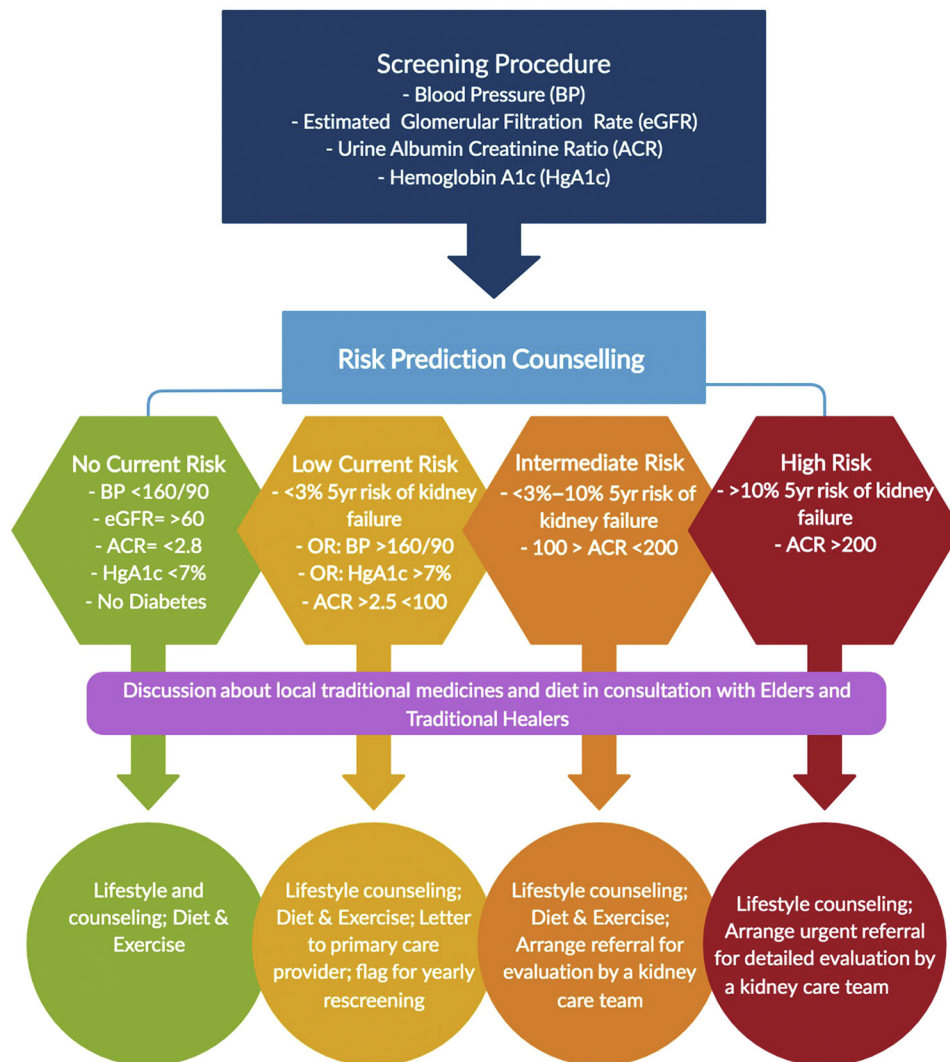
Indigenous peoples often endure significant health disparities fueled by historic and ongoing marginalizing policies and practices. In many cases, Indigenous groups are isolated from mainstream health care services (geographically, economically, or culturally) and lack the preventive health benefits associated with continuity of care.<sup>1</sup> In Canada, this manifests in disproportionately high rates of chronic disease, often diagnosed at a younger age and greater severity than non-Indigenous groups. Of these, chronic kidney disease (CKD), diabetes, and hypertension are highly prevalent, reaching epidemic levels in many communities.<sup>2</sup>

Kidney Check is a comprehensive screen, triage, and treat initiative working to bring preventive kidney care to rural and remote Indigenous communities across Manitoba, Ontario, British Columbia, Alberta, and Saskatchewan. Modeled after the 2015 FINISHED initiative in Manitoba,<sup>3</sup> and working within the CanSOLVE CKD network ([www.cansolveckd.ca](http://www.cansolveckd.ca)), Kidney Check employs point-of-care testing (POCT) to identify CKD, diabetes, and hypertension in individuals aged 10 and up regardless of preexisting

risk factors. To ensure the efficacy and sustainability of the program, Kidney Check relies on a strategic quality management system that addresses all aspects of the screening process. The intent of this manuscript is to describe the development process of all procedures and components related to the deployment of the Kidney Check program with specific focus on organizational structure, point-of-care testing devices, and data management.

## The Kidney Check Team

Kidney Check's management structure consists of the leadership team, advisory committee, patient partner committee, and mobile screening teams. Leadership provides guidance to the provincial teams to ensure the appropriate objectives, processes, and tools are in place to support high-functioning groups. This includes working closely with the advisory committee to preemptively identify potential barriers and risk issues in order to develop efficient mitigation strategies. Largely composed of Indigenous stakeholders and closely affiliated with the CanSOLVE CKD Indigenous People's Engagement Council (IPERC), the advisory

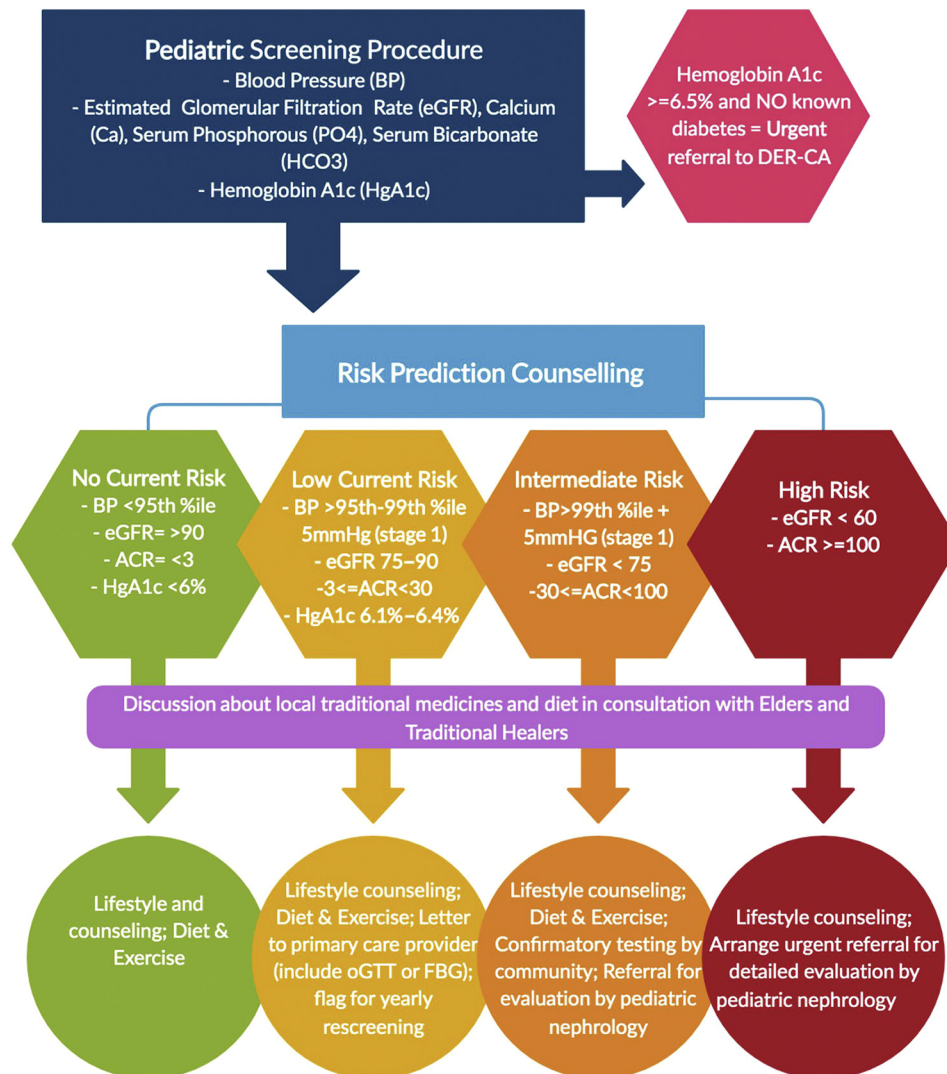


**Figure 1.** Adult Kidney Check screening process. Blood pressure (BP) guidelines are used to diagnose risk of developing chronic kidney disease (CKD) not hypertension; that is, if BP is between the recommended target of 140 to 160 mm Hg, the patient should be followed up for hypertension but is not at current risk of developing CKD.

committee provides valuable insight on how to best use engagement strategies to maximize participation in the screening event. They are supported by the patient partner committee that oversees the execution of knowledge translation activities including but not limited to community selection criteria, community engagement procedures, and review of communication materials and strategies. Screening teams operate under the auspices of the Diabetes Integration Project and First Nations Health and Social Secretariat of Manitoba (FNHSSM). Stationed in various communities across the country, the team's primary aim is to accommodate high throughput while maintaining quality control (QC) standards. As an affiliate of the CanSOLVE CKD network, members of all committees within Kidney Check have linkages to the broader network.

### The Screening Process

The screening process (Figures 1 and 2) was designed in collaboration with a process engineer to facilitate greater throughput while maintaining a high level of QC. All members of the community who want to participate in the screening program are welcome to do so. Prior to screening, clients' complete registration and provide consent. Consent is obtained for the screening itself and to allow project team members access to lab and health care utilization data at a later date. A legal guardian may provide consent for a child (<18 years old), and assent is obtained from the child themselves prior to screening. Baseline demographic information (personal health number, date of birth, and name of home community), height, weight, and body mass index are recorded for each client. An average blood pressure is determined using 6 measurements taken over 6 minutes according to



**Figure 2.** Pediatric Kidney Check screening process.

best practice outlined by the Canadian Hypertension Education Program (CHEP).<sup>4</sup>

Following registration, clients are brought to a designated screening area where a finger prick droplet sample (100  $\mu$ L) is collected and analyzed for creatinine on an i-STAT Alinity analyzer (Abbott Point of Care Inc., Princeton, NJ). An additional blood sample (100  $\mu$ L) is collected to analyze for hemoglobin A<sub>1c</sub> and a urine sample is provided to determine the albumin-to-creatinine ratio on a DCA Vantage analyzer (Siemens, Erlangen, Germany). Client consents, demographic information, and clinical data are entered at the point of care onto an iPad using a secure, customized application designed specifically for Kidney Check. Once a client's information is entered, the application automatically calculates their risk of progressing to end-stage kidney disease using the Kidney Failure Risk Equation. Validated in more than 700,000 adults across 30 countries, the Kidney Failure Risk Equation predicts the 2- and 5-year probability of requiring dialysis or transplant for

individuals whose estimated glomerular filtration rate was  $<60$  ml/min per  $1.73$  m<sup>2</sup>. The 4-variable equation includes age, sex, estimated glomerular filtration rate, and urine albumin-to-creatinine ratio whereas the 8-variable equation further incorporates serum albumin, phosphate, calcium, and bicarbonate levels.<sup>5</sup> Adult clients are triaged according to their Kidney Failure Risk Equation score and/or level of proteinuria (for those with an estimated glomerular filtration rate  $>60$  ml/min per  $1.73$  m<sup>2</sup>) as high, intermediate, or low risk. Pediatric ( $<18$  years old) clients are triaged using a separate algorithm developed in collaboration with pediatric nephrologists and endocrinologists.<sup>3</sup>

Every client receives risk-based kidney health counseling from the screening nurse immediately following testing. Developed in collaboration with Indigenous patient partners, the counseling scripts provide a concise outline of each client's current risk and what steps need to be taken going forward to preserve kidney health. These discussions uphold the

principles of shared decision making and incorporate local traditional medicines and diet in consultation with Elders and traditional healers. Primary care providers are contacted with their clients' results and provided with a treatment plan, including special recommendations for pediatric patients. All intermediate- and high-risk patients are immediately referred to a multidisciplinary kidney health clinic where they are able to consult with a nephrologist, dietician, and pharmacist to design a treatment plan.

## Quality Management Program

### *Preanalytical Quality and Staff Competency*

Shared Health Diagnostic Services oversees the quality management program that is based on the Accreditation Canada Qmentum Guidelines on Point-of-Care Testing.<sup>6</sup> They are responsible for administering initial training and competency assessments to new POCT device operators and ensuring current operators are recertified annually. Initial training includes information on preanalytical processes, POCT system operations, the principles and procedures of QC, documentation requirements, and basic troubleshooting as appropriate. An annual competency assessment of authorized testing personnel must meet the minimal requirements as stated by Clinical Laboratory Improvement Amendments (CLIA) and Accreditation Canada Qmentum Guidelines on Point-of-Care Testing.<sup>6</sup> Only staff whose training and competence has been established, recorded, and regularly updated are permitted to perform, maintain, and supervise screening.

### *Instrument QC*

QC procedures ensure the day-to-day precision of POCT by detecting, reducing, and correcting errors in the analytical process. QC checks are done prior to patient testing, after changing the reagent cartridge lot number and any time there is suspicion the analyzer is not working correctly. Cartridges are checked on delivery with multiple levels of the manufacturer's QC verifiers to ensure they perform to specifications and were not damaged in transit. Different lot numbers and cartridge types must be checked separately. The analyzer component of each device is checked with the manufacturer's electronic simulator on every day of use prior to patient testing. Testing procedures include provisions for troubleshooting when a QC result is out of range. All QC procedures, including any corrective actions taken, are logged and retained for a minimum of 2 years to ensure traceability.

### *i-STAT Alinity*

The i-STAT Alinity (Abbott Point of Care Inc., Princeton, NJ) is a handheld diagnostic device designed to perform blood analysis at the point of care. The analyzer automatically controls all functions of the testing cycle, including a calibration sequence run

prior to testing patient samples. Abbott reissues calibration values (CLEW updates) periodically to maintain long-term consistency of results over a range of cartridge lot numbers. New CLEW updates reestablish the standardization of the device and incorporate refinements to the internal quality-monitoring system.<sup>7</sup> The electronic simulator is an independent QC device for the analyzer. The simulator produces signals at 2 levels to check both the accuracy and sensitivity of the electrical measurement circuitry and the electrical isolation between individual measurement channels.

### *DCA Vantage*

The DCA Vantage is used to quantitatively measure glycated hemoglobin (HbA<sub>1c</sub>) in blood, and the albumin-to-creatinine ratio in urine. The DCA Vantage consists of a spectrophotometer and precalibrated cartridges containing both wet and dry reagents. Each patient test is a single reagent cartridge identified by specific barcoded cards containing all chemistry parameters and calibration factors.<sup>8</sup> Once an operator scans a calibration card, the system automatically sets the calibration for the entire lot of reagent cartridges. Operators are able to access the appropriate calibration parameters and calibration curve by scanning the lot number and test name prior to sample analyses. QC checks are run on each day of analyzer operation prior to patient testing using Bio-Rad Liquichek Diabetes Control Level 1 and 2 (Bio-Rad Laboratories, Inc.).

## External Proficiency Testing

When applied to POCT, external proficiency testing is designed to provide regular, independent assessments of an *in vitro* medical device to ensure results meet quality standards. Subscribing to an external proficiency program is a critical component of an overall quality management system, providing a comprehensive review of the program's entire quality assurance process.<sup>9</sup> Kidney Check subscribes to an external proficiency testing program through the College of American Pathologists (<https://www.cap.org/laboratory-improvement/proficiency-testing>). This choice allows for alignment with the provincial clinical laboratories, providing for greater comparability and ease of troubleshooting. Challenge samples are sent to be analyzed twice each year, with 3 samples spanning different measurement ranges. These results, when properly reviewed and understood, may provide significant actionable insights which in turn drive continuous quality improvement.

## Data Management and Ownership, Control, Access, and Possession

Kidney Check prioritizes the confidentiality, privacy, and security of all health data gathered throughout the

program. These data are recorded via the Kidney Check application, developed in partnership with eQOL Inc., a Canadian health technology company, Indigenous project team members, and patient partners. The company has undertaken all of the privacy risk and threat assessments required to securely store health data and has been approved in multiple jurisdictions throughout Canada. Client information is routinely backed up to the Canadian server it is held on, with contingency measures in place to remotely wipe all records held on any device should it be misplaced. Both the application and the tablet computers are password protected, with mandatory single-user logins to facilitate auditing procedures. At project completion, all data will be pulled from the mainframe server and given to the proper Indigenous custodians in each province, as well as each community, if desired. In doing so, the program upholds the First Nations principles of Ownership, Control, Access and Possession that dictate how Indigenous data are to be collected, stored, and shared. A response to previous misuse of Indigenous research findings, the Ownership, Control, Access and Possession principles promote self-determination and capacity development as they relate to health care.<sup>S10</sup>

## CONCLUSION

Kidney Check is a screening program working to bring culturally safe preventive education and care to rural and remote Indigenous communities across Canada. It is an important program of work integrated within the CanSOLVE CKD Network for implementation and knowledge translation activities. Operational tasks are delegated among 4 working groups whose unique functions each contribute to the success of the program. Indigenous partners provide valuable insight into the unique perspectives and needs of Indigenous peoples, ultimately guiding the program's design and delivery. To promote the efficacy and sustainability of the program, Kidney Check is accountable to a comprehensive quality management system that includes internal as well as external QC processes. These processes are dictated by standard operating procedures and include the regular maintenance of POCT devices and routine competency assessments for device operators as well as troubleshooting resources. Regular external proficiency testing further ensures that patient results can be confidently used to guide clinical decision making and promotes continuous quality improvement. The program was externally evaluated as successfully benefiting First Nations people, providing

comprehensive screening, education, and referral to nephrology where appropriate in a cost-effective manner.<sup>S11</sup> All data collected throughout the program is securely managed according to the Ownership, Control, Access and Possession principals and local and national privacy standards. Currently, Kidney Check is working toward trademarking the program. This would ensure all future Kidney Check partners uphold and standardize the principles of cultural safety, patient involvement, and QC standards the program was built on.

## DISCLOSURE

All the authors declared no competing interests.

## ACKNOWLEDGMENTS

This study was funded by the Canadian Institutes of Health Research (CIHR), CanSOLVE CKD network, and TD Competition.

## SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Supplementary References.

## REFERENCES

1. Marrone S. Understanding barriers to health care: a review of disparities in health care services among indigenous populations. *Int J Circumpolar Health*. 2007;66:188–198.
2. Yeates K, Tonelli M. Indigenous health: update on the impact of diabetes and chronic kidney disease. *Curr Opin Nephrol Hypertens*. 2006;15:588–592.
3. Lavallee B, Chartrand C, McLeod L, et al. Mass screening for chronic kidney disease in rural and remote Canadian first nations people: methodology and demographic characteristics. *Can J Kidney Health Dis*. 2015;2:9.
4. Hypertension Canada. Canadian Hypertension Education Program. Available at: <https://guidelines.hypertension.ca/diagnosis-assessment/measuring-blood-pressure/>. Published 2014. Accessed June 12, 2020.
5. Lerner B, Desrochers S, Tangri N. Risk prediction models in CKD. *Semin Nephrol*. 2017;37:144–150.
6. Accreditation Canada. Qmentum point-of-care testing standards. Available at: [store.accreditation.ca/products/point-of-care-testing](https://store.accreditation.ca/products/point-of-care-testing). Accessed January 14, 2021.
7. Lee MY, Lim S, Lam L. Evaluation of the i-STAT Alinity Point-of-Care Analyzer. *Point Care*. 2019;18:48–55.
8. Szymezak J, Leroy N, Lavalard E, et al. Evaluation of the DCA Vantage analyzer for HbA1c assay. *Clin Chem Lab Med*. 2008;46:1195–1198.
9. Richardson H, Gun-Munro J, Petersons A, Webb S. External quality assessment in the quality management of POCT. *Point Care*. 2005;4:164–166.