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# Community Pharmacy-Based eGFR Screening for Early Detection of CKD in High Risk Patients

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## Abstract

**Background:** Chronic kidney disease (CKD) is a condition presenting with long-term slow progression of structural and/or functional damage to the kidneys. Early detection is key to preventing complications and improving outcomes. Point-of-care estimated glomerular filtration rate (eGFR) screening technology allows for detection of abnormal kidney function in the community pharmacy setting.

**Objective:** To evaluate the effectiveness of a community pharmacist-directed point-of-care screening program and to identify the prevalence of CKD in high-risk patients.

**Design:** Quantitative observational.

**Setting:** Four community pharmacies in British Columbia over a 6-month period.

**Patients:** In all, 642 participants with at least one CKD risk factor were identified and screened. Mean age was 60 years and females accounted for 55% of the study population.

**Measurements:** Serum creatinine was measured from peripheral blood using the HeathTab® screening system (Piccolo® Renal Function Panel with the Piccolo® blood chemistry analyzer). eGFR was calculated according to the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.

**Methods:** Patients provided a sample of peripheral blood via a self-administered finger-prick and analytical data to assess kidney function was reported including blood urea nitrogen (BUN), serum creatinine, and electrolytes by the HealthTab® screening system. Once results were available, the pharmacist conducted a comprehensive medication review with the patient and recommended certain follow-up actions if appropriate.

**Results:** CKD risk factor included diabetes (30%), hypertension (45%), cardiovascular disease (12%), family history of kidney disease (13%), age over 55 years (68%), and an Aboriginal, Asian, South Asian, or African ethnic background (82%). A total of 11.5% of patients had eGFR values lower than 60 mL/min (abnormal renal function) and 34% had an eGFR between 60 and 89 mL/min (minimally reduced renal function). Overall pharmacists' actions included blood pressure check (98%), education on CKD and risk factors (89%), medication review (72%), and physician follow-up (38%). Limitations included lack of follow-up beyond the 3-month study period prevented medical confirmation of CKD and limited the ability to quantify the impact of pharmacist interventions on the clinical outcomes of patients with low eGFR.

**Conclusion:** These results illustrate the prevalence of abnormal renal function among undiagnosed, high-risk patients in the community. Pharmacists, as the most accessible healthcare practitioners, are ideally positioned to utilize novel point-of care technologies to improve access to CKD screening, facilitate follow-up, and increase awareness around the importance of early detection.

## Abrégé

**Contexte:** L'insuffisance rénale chronique (IRC) est caractérisée par la progression lente et à long terme de lésions rénales structurelles et/ou fonctionnelles. Son dépistage précoce est essentiel pour prévenir les complications et améliorer l'issue des patients. La détection d'une fonction rénale anormale en pharmacie d'officine est rendue possible grâce aux technologies de mesure du DFGe hors laboratoire.

**Objectif:** Évaluer l'efficacité d'un program de dépistage de l'IRC dirigé par les pharmaciens d'officine et établir la prévalence de l'IRC chez les patients présentant un risque élevé.

**Type d'étude:** Étude quantitative observationnelle

**Cadre:** L'étude s'est tenue dans quatre pharmacies d'officine de Colombie-Britannique sur une période de six mois.

**Sujets:** Un total de 642 individus présentant au moins un facteur de risque d'IRC ont fait l'objet d'un dépistage. L'âge moyen se situait à 60 ans et 55 % étaient des femmes.
**Mesures:** La créatinine sérique a été mesurée à partir d'un prélèvement de sang périphérique à l'aide d'un système de criblage HealthTabMD (bilan de la fonction rénale avec l'outil d'analyze chimique du sang PiccoloMD). Le DFG a été estimé à l'aide de l'équation CKD-EPI.
**Méthodologie:** Les patients ont fourni un échantillon de sang périphérique autoprélevé par piqûre au doigt. Les données analytiques pour l'évaluation de la fonction rénale, soit les taux d'azote uréique sanguin (BUN), de créatinine sérique et d'électrolytes, ont été obtenues à l'aide du système de criblage HealthTab$^{MD}$. Après l'obtention des résultats, le pharmacien a procédé à une revue de la médication avec le patient et recommandé des mesures de suivi lorsque nécessaire.
**Résultats:** Le diabète (30 %), l'hypertension (45 %), les maladies cardiovasculaires (12 %), le fait d'avoir des antécédents familiaux de néphropathie (13 %), d'être âgé d'au moins 55 ans (68 %) ou d'être d'origine autochtone, asiatique, sud-asiatique ou africaine (82 %) constituaient les facteurs de risque. Des 642 participants, 11,5 % présentaient une fonction rénale anormale (DFGe inférieur à 60 ml/min) et 34 % présentaient une fonction rénale réduite (DFGe entre 60 et 89 ml/min). Les interventions des pharmaciens incluaient la mesure de la pression artérielle (98 %), l'éducation sur l'IRC et ses facteurs de risque (89 %), la revue des médicaments (72 %) et le suivi médical (38 %).
**Limites:** L'absence de suivi au-delà des trois mois de l'étude n'a pas permis de confirmer l'IRC ni de mesurer la portée des interventions des pharmaciens sur les résultats cliniques des patients présentant un faible DFGe.
**Conclusion:** Ces résultats illustrent la prévalence d'une fonction rénale anormale dans la communauté chez les patients non diagnostiqués présentant un risque élevé. Les pharmaciens, en tant que professionnels de la santé les plus accessibles, sont les mieux placés pour utiliser les technologies d'intervention au point de service et ainsi améliorer l'accès au dépistage de l'IRC, faciliter le suivi et sensibiliser la communauté à l'importance du dépistage précoce de la maladie.

**Keywords**
CKD (chronic kidney disease), early detection, community pharmacy, point of care screening, pharmacy practice

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## What was known before

Targeted screening has identified a high proportion of individuals with risk factors for CKD and a high prevalence of unrecognized CKD.

## What this adds

This is the first study is to evaluate the effectiveness of a community pharmacist-directed point-of-care screening program to identify the prevalence of CKD in high-risk patients.

## Introduction

Chronic kidney disease (CKD) is defined as irreversible renal damage or loss of kidney function lasting more than 3 months and typically progresses slowly over a period of months to years.[1] Renal damage is defined by markers of disease including albuminuria, an albumin to creatinine ratio (ACR) of more than 3 mg/mmol; haematuria; tubular disorders; and histological or structural abnormalities.[1] Loss of renal function is characterized by a creatinine clearance or an estimated glomerular filtration rate (eGFR) of less than 60 mL/min/1.73 $m^2$.[1,2]

Roughly 10% of Canadians live with CKD and prevalence increases to 22% in those who are 70 years or older.[3] Ninety percent of CKD patients go undiagnosed, likely because early symptoms are uncommon or non-specific.[4] This allows the condition to progress without detection until later stages and is often identified during stage 5 CKD (eGFR $<$ 15 mL/min) or fulminant kidney failure.[4,5] Patients with later stages of CKD may experience weight loss, vomiting, anorexia, pruritis, or muscle cramps, and frequently require hemodialysis or transplantation. Complications of CKD and subsequent end-stage renal disease (ESRD) include anemia, bone disorders, and increased risk of cardiovascular disease

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and premature all-cause mortality.[5] Hemodialysis, required for patients with stage 5 CKD, currently costs Canadians $60,000 per patient per year or $260 million annually in disability payments by the public healthcare system.[6,7]

HealthTab® is a point-of care health screening system designed for use in ambulatory settings including community pharmacies that can alert some of these patients about their declining kidney function before it reaches the point of complications.[8] It combines a lab accurate analyzer with a user-friendly interface and secure online portal.[9] With a 400 dollar per month rental, the Healthtab® system costs only 12 dollars per test. The Piccolo Xpress® Comprehensive Metabolic Panel developed by Abaxis® can directly determine a patient's aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), albumin, calcium, chloride, creatinine, glucose, potassium, sodium, total bilirubin, total carbon dioxide, total protein, and blood urea nitrogen (BUN) from a sample of peripheral blood. The analysis takes under 15 minutes, and patients have permanent access to their results securely online.[10]

Diabetes, cardiovascular disease, hypertension, and age greater than 55 are known risk factors for developing CKD.[11] There are also known ethnic variations in risk, and risk increases with a family history of the disease.[11,12] The primary objective of this study is to evaluate the effectiveness of a community pharmacist-directed point-of-care screening program using HealthTab® technology to identify the prevalence of CKD in high-risk patients. The secondary objective of this study was to determine which risk factors for CKD were most effective in predicting previously undiagnosed loss of kidney function in the community pharmacy setting.

## Methods

The study was performed at 4 different Medicine Shoppe community pharmacies in British Columbia recruited by random, voluntary selection between July 7, 2014, and January 31, 2015. Eligible patients had at least one of the following CKD risk factors—hypertension, cardiovascular disease, diabetes, family history of renal disease, age over 55 years, or a high-risk ethnicity and were identified during a medication review. Staff pharmacists obtained patient consent and facilitated use of the HealthTab® screening system using an on-site Piccolo® Comprehensive Metabolic Panel and blood chemistry analyzer. Once data were obtained, patient consent was obtained to assign a unique participant ID to ensure confidentiality and anonymity and use the patient data for research purposes. Ethics approval was not required as the screening was already a routine clinical service within these locations, and patients were simply offered the opportunity to share their demographic and result information anonymously.

Patients created a secure participant profile on the HealthTab© interface and uploaded their demographic information. A sample of venous blood from a self-administered fingerstick using a disposable lancet after sanitizing with an alcohol swab was provided. The first drop of blood was wiped off to avoid extensive hemolysis. Subsequent drops were gathered in a collection tube via capillary action and gentle finger squeezing along the puncture site until a minimum sample of 100 μL was collected. The pharmacist then pipetted the sample into a metabolic panel disk for analysis by the Piccolo® device. Once in the panel disk, the blood was heparinized and centrifuged into cuvette wells containing dry sample blank reagent beads comprised of buffers, surfactants, excipients, and varying reagents required for analysis by absorption chemistry.[10]

The Piccolo® blood chemistry analyzer calculates the eGFR for each patient based on entered age, sex, and race, and the panel-determined creatinine levels using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) study equation.[10,13]

The concentration of serum creatinine (sCr) in this equation was determined by the analyzer by measuring the intensity of the red color produced once blood creatinine had undergone a 4-step reaction with reagents and enzymes included in the metabolic panel.[10]

Based on publicly available data from the American Proficiency Institute (https://www.api-pt.com/), results from the Piccolo including creatinine are consistently in close agreement with the reported results from many of the top laboratory instruments. When examining the coefficient of variation for creatinine, the Piccolo demonstrates good precision at clinically significant concentrations (CV ~4%-12%).

Results were typically available within 10 to 15 minutes. Normal renal function was defined by an eGFR of 90 or greater. Mildly reduced renal function was defined as an eGFR of 60 to 89 (CKD Stage 2), whereas significantly reduced renal function was defined as an eGFR of 30 to 59 (CKD Stage 3). During this time, each participant completed a paper-based questionnaire that collected information on demographics (age, gender, and ethnicity) and lifestyle and health characteristics (tobacco use, exercise, body mass index [BMI], and history of diabetes/hypertension/kidney disease), which provided us with information further to the individual risk factor for which they were selected to participate. The pharmacist also conducted a comprehensive medication review with the patient and recommended appropriate follow-up actions such as lifestyle modifications and/or referral to their family physician as necessary. These recommendations were based on the individual clinical judgment using the patients medication history and risk factors. Submitted data were pooled and analyzed using descriptive statistics. Descriptive statistics were provided using mean (±SD) or median (range) values depending on the (non-) parametric distribution of measured variables. Relative risk of a significantly reduced eGFR result was calculated for each risk factor using the equation $\frac{a}{a+b} \div \frac{c}{c+d}$, where $a$ and $c$ were the number of patients having an eGFR value less than 60 with or without the risk factor, respectively, and $c$ and $d$ were the risk of having an eGFR above 60, with or without the risk factor, respectively. The risk factors of obesity and vascular disease were also considered in these

**Table 1.** Patient Demographics and Summary of CKD Results (mL/min).

| Number of participants (%) | | | | | Overall |
|---|---|---|---|---|---|
| Gender | Females | | | | 353 (55%) |
| Age | ≤35 | | | | 35 (10%) |
| | 36-54 | | | | 81 (23%) |
| | 55+ | | | | 236 (67%) |
| Ethnic background | South Asian | | | | 372 (58%) |
| | East or Southeast Asian | | | | 116 (18%) |
| | Caucasian | | | | 128 (20%) |
| | Aboriginal, African, Latin American or other. | | | | 26 (4%) |
| By GFR screening results | eGFR 90+ | 60-89 | 30-59 | 15-29 | Overall |
| Total study population | 356 (55%) | 215 (33%) | 68 (11%) | 3 (0.5%) | 642 |
| Age 55+ | 164 (45%) | 183 (85%) | 62 (91%) | 3 (100%) | 412 (64%) |
| Family history of CKD | 43 (12%) | 28 (13%) | 8 (12%) | 1 (33%) | 80 (12%) |
| Ethnic background | 331 (93%) | 140 (65%) | 41 (60%) | 2 (67%) | 514 (80%) |
| Diabetes | 85 (24%) | 73 (34%) | 28 (41%) | 3 (100%) | 189 (29%) |
| Hypertension | 110 (31%) | 118 (55%) | 49 (72%) | 2 (67%) | 279 (43%) |
| Vascular disease | 25 (7%) | 26 (12%) | 11 (16%) | 1 (33%) | 77 (12%) |
| Overweight or obese | 196 (55%) | 127 (59%) | 31 (45%) | 2 (67%) | 360 (56%) |

*Note.* CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate.

**Table 2.** Patient Risk Factors and Relative Loss of Kidney Function Risk.

| Risk factor and eGFR (mL/min) | | eGFR 60+ | eGFR < 60 | Relative risk (confidence interval) | *P*-value |
|---|---|---|---|---|---|
| Total study population | 642 | 571 | 71 | | |
| Age 55+ | 412 (64%) | 347 | 65 | 6.04 (2.66-13.74) | <.0001 |
| Family history of CKD | 80 (12%) | 71 | 9 | 1.02 (0.53-1.97) | .9536 |
| Ethnic background | 514 (80%) | 471 | 43 | 0.38 (0.25-0.60) | <.0001 |
| Diabetes | 189 (29%) | 158 | 31 | 1.86 (1.20-2.88) | .0055 |
| Hypertension | 279 (43%) | 228 | 51 | 3.32 (2.03-5.43) | <.0001 |
| Vascular disease | 77 (12%) | 51 | 12 | 1.87 (1.06-3.28) | .0296 |
| Overweight or obese | 360 (56%) | 323 | 33 | 0.70 (0.45-1.08) | .1085 |

*Note.* eGFR = estimated glomerular filtration rate; CKD = chronic kidney disease.

calculations, though they were not used explicitly in screening patients. One limitation was that since all patients had at least one of the listed risk factors, the control values of *b* and *d* included patients with any number of other risk factors, as long as they did not have the risk factor for which the relative risk was being calculated.

Three of the pharmacists recruiting and screening patients in the study were surveyed after the study on the amount of time they felt the process took to perform, and the recommendations and interventions performed by pharmacists were recorded.

## Results

Patient demographics and calculated eGFR are summarized in Table 1. A total of 642 patients were screened over a 6-month period and were included in the analysis. The mean age was 60 years, and participants ranged from 20 to 102 years. The female and male proportions were 55% and 45%, respectively. In all, 11.5% of the patients had CKD stage 3 or higher. Fifty-five percent of the participants presented with normal adult renal function (eGFR 90+ mL/min). Thirty-three percent of participants had eGFR between 60 and 89 mL/min. CKD stage 3 was detected in 11.5% of participants. Three participants had eGFR between 15 and 29 mL/min. Of the patients with abnormal renal function (eGFR < 60), 77% did not have a reported history of CKD.

The two most common risk factors of participants were ethnic background (80%) and age over 55 (67%). Other CKD risk factors included diabetes (30%), hypertension (45%), cardiovascular disease (12%), family history of kidney disease (13%), age over 55 years (68%), and an Aboriginal, Asian, South Asian, or African ethnic background (82%).

The prevalence of each CKD risk factor relative to eGFR is outlined in Table 2. Age greater than 55 was most closely correlated to a reduced eGFR. These patients were 6 times

more likely to present with an eGFR less than 60. Other significant risk factors include hypertension with greater than 3 times the relative risk and diabetes with nearly twice the relative risk. Family history of CKD or obesity did not show any significant correlation with poor eGFR. Interestingly, ethnic background showed a negative correlation with reduced renal function. This group included a diverse population of Aboriginal, Asian, African, or South Asian patients, and only 7% of all participants (n = 128) were not considered to be of an identifiable ethnicity. In addition, 58% of those considered to be of ethnic background were South Asian, and a relatively small portion were Aboriginal, though Aboriginals compose a large portion of Canada's program participants.

Pharmacists performed interventions relevant to the individual's loss of kidney function by checking blood pressure, providing information about CKD, and conducting a comprehensive medication review. Pharmacists also used the opportunity to engage in health promotion commonly recommending a healthier diet and increased physical activity. Smoking cessation counseling was offered to 6% of patients. Of the 3 pharmacists surveyed after the study, the complexity of the process was rated as 2 on a scale out of 5, where 1 was "not time-consuming at all" and 5 was "very time-consuming."

Pharmacists recommended that 39% of all participants screened see their family physician for follow-up, which included 100% of those with renal function <30 mL/min and 81% of participants with renal function between 30 and 60 mL/min. Surprisingly, most of these patients (92%) reported seeing their physician at more than one office visit per year.

## Discussion

This pilot program provided insight into the effectiveness of the community pharmacist-directed point-of-care screening program to identify abnormal renal function among high-risk patients using HealthTab® technology. Detection of reduced renal function was most closely associated with age over 55 years, hypertension, and diabetes (Table 2). Those considering offering a CKD screening service may want to focus their efforts on these patient populations. Vascular disease was also associated with a nearly double increase in risk (risk ratio [RR]: 1.87), but the category itself was not well-defined.

In addition to identifying those patients with significant renal dysfunction, targeting patients with risk factors for CKD provides a unique opportunity to engage in health promotion and education. Pharmacists often recommended a healthier diet and an increase in physical activity. These types of recommendations are instrumental in reducing risk from hypertension, vascular disease, diabetes, and obesity. Screening also afforded pharmacists the opportunity to check the blood pressure of almost all patients and intervene accordingly. Finally, a small subset of patients did not require any intervention as they had eGFRs which were only slightly reduced and were most likely related to normal age-related renal function decline (0.05-1.5 mL/min/year).[14] These recommendations are in line with the Kidney Disease Improving Global Outcomes (KDIGO) 2012 Clinical Practice Guideline for evaluating and intervening for patients with CKD. These guidelines rely on population-based studies which demonstrate the increased risk of death and cardiovascular mortality as GFR falls below 60 mL/min.[15]

Clinical practice guidelines recommend screening for CKD to enable early identification and intervention, with the goal of slowing progression and preventing complications.[16] In 2016, the SeeKD study, screened 6 329 patients with at least one CKD risk factor and was able to identify 18.8% of patients with previously undiagnosed CKD. The authors suggested a possible benefit of targeted screening.[17] In SeeKD specifically, patients were recruited from community centers, churches, and senior's residences.[17] A number of studies have already demonstrated the positive impact pharmacists can have when implementing point-of-care technology screening for both chronic and acute care disease state management.[18-20] As such, pharmacists in community practice, as the most accessible healthcare practitioners, may be ideally positioned to improve access to CKD screening and increase awareness around the importance of early detection. Previous studies have used point-of-care technology to evaluate CKD risk assessment in community pharmacies; however, this study was the first to evaluate the relative strength of risk factors in predicting and identifying CKD issues.[21]

Moreover, 72% of patients had their medication regimen reviewed by a pharmacist. This is instrumental in helping to identify and differentially diagnose medication-related causes of CKD, in ruling out acute kidney injury requiring immediate medical attention, and identifying other drug-related problems. A systematic review of 49 studies from 23 countries identified inappropriate prescribing events involving renally excreted drugs in CKD patients as a frequent issue in both hospital and ambulatory settings.[22] The risk of adverse drug events was 32% lower in patients whose medications or dosages were adjusted by pharmacists.[22] Although potentially beneficial to all patients, comprehensive medication reviews by pharmacists may be especially useful in those that have been identified as having reduced kidney function by community-based screening.

Despite the recommendation by many clinical practice guidelines for regular renal function monitoring in patients with CKD or those at high risk, adherence to scheduled physician screenings still only ranges from 28% to 75%.[23] Community pharmacies offer the convenience and accessibility that could serve to increase the number of patients that receive testing.[24] Anecdotally, pharmacists reported that CKD screening provided value to patients, could be successfully incorporated into the workflow, and served to differentiate the services offered by their pharmacy. No additional employees were required to provide this service. With a 400-dollar per month rental, the Healthtab® costs only an additional twelve dollars per test, and cost would be expected to decrease with widespread use. The complexity of the process was rated as "not very time consuming" by pharmacists recruiting, screening, and performing interventions in this study. Simplicity seemed to be based on previous familiarity with the Healthtab®

system, the extend of formal training, and the presence of an assistant who could perform technical tasks such as preparing the patient before collecting the blood sample, introducing the Healthtab® system, and measuring the patients' blood pressure. This allowed the pharmacist to focus on cognitive functions including interpretation of blood test results, patient education, conducting medication reviews, and recommending follow-up actions. Pharmacists also reported that most of the participants were very interested in the program and appreciated the one-on-one time with the pharmacist.

The primary limitation of the study was the lack of follow-up at the end of the 3-month period, which would have allowed for a confirmation of CKD. As a time-dependent disease, CKD cannot be diagnosed from a single eGFR reading. Measuring renal function allows us to identify those patients who are either at risk of developing CKD or who may have CKD and require further investigation for renal damage or prolonged loss of function.[23] The lack of follow-up also limited the ability to quantify the impact of pharmacists' interventions on patients with low eGFR. There is a correlation between low GFR levels, cardiovascular disease hospitalization, and risk of death.[5,25] The KDIGO 2012 guideline recommendations classify CKD by both GFR and albumin in order to obtain a more accurate assessment of CKD.[23] Unfortunately, urine samples could not be collected and analyzed in the pharmacy in order to allow for classification of patients with reduced function by the KDIGO categories. A final limitation was the inclusion of 26 patients screened in the community who were aware of their CKD diagnosis but participated because they did not know their current GFR. Fortunately, this represented only a very small proportion of our patient population (4%).

Overall, these results illustrate that the prevalence of abnormal renal function among undiagnosed, high-risk patients in the community is indeed high. In all, 11.5% of patients had eGFR values lower than 60 mL/min, and this number resembles that of previous studies in both the community and laboratory settings.[4,6] We suggest the most successful pharmacy community screening programs in the future would target those patients with advanced age, hypertension, and/or diabetes. Pharmacists, as the most accessible healthcare practitioners, are ideally positioned to utilize novel point-of care technologies to improve access to CKD screening, educate patients about CKD, and increase awareness around the importance of early detection.

## Ethics Approval and Consent to Participate

Investigators obtained informed consent from all participants.

## Consent for Publication

Not applicable as there is no patient identifying information in this manuscript.

## Availability of Data and Materials

The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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