Community pharmacist identification of chronic kidney disease using point-of-care technology: A pilot study

Jacqueline Donovan, BMedSci, MPharm^{ID}; Yazid N. Al Hamarneh, BSc(Pharm), PhD^{ID};

Beata Bajorek, BPharm, DipHospPharm, GradCertEdStud(HigherEd), PhD; John Papastergiou, BSc, BScPhm;

Ross T. Tsuyuki, BSc(Pharm), PharmD, MSc, FACC, FCSHP, FCAHS

Introduction

The global burden of chronic kidney disease (CKD) is increasing, affecting between 3% and 18% of the population when applying the Kidney Disease Improving Global Outcomes (KDIGO) and the Kidney Disease Outcomes Quality Initiative (KDOQI) definitions.¹ In Canada alone, it is estimated to affect approximately 12.5% of the adult population.² Similarly, it is estimated to affect 10% of the Australian population. CKD occurs when there is a permanent reduction in renal function (i.e., an estimated glomerular filtration rate [eGFR] <60 mL/min/1.73 m²) or other markers of kidney damage (i.e., albuminuria ≥3 mg/mmol or abnormalities in urine sediment or renal imaging) persisting for more than 3 months.¹ Furthermore, CKD is more broadly an independent risk factor for hypertension and cardiovascular disease, thereby contributing to the high morbidity and mortality rates within the general population.¹

Early intervention is key to reducing the morbidity and mortality attributed to CKD.³ However, clinical guideline recommendations for prompt identification of CKD are challenged by the fact that the early stages of CKD are often asymptomatic. In the primary care setting, a large proportion of patients are undiagnosed and/or undertreated.⁴ For this reason, targeted and accessible screening of high-risk patients, such as those with hypertension, diabetes, family history of kidney disease and cardiovascular disease, is needed.⁵

To this end, community pharmacists are at the forefront of primary care and in an optimal position to provide such targeted screening for CKD. Indeed, targeted screening, in conjunction with the implementation of the CKD Clinical Pathway,⁵ is one initiative that has already been evaluated in

Alberta, Canada.⁶ In that study, Al Hamarneh et al.⁶ used the pharmacists' authority to view, order and interpret laboratory tests⁷ to screen 720 high-risk patients for CKD as per the CKD Clinical Pathway.⁵ They found that 40% of those screened had CKD, and of those, 40% had *previously unrecognized* CKD (i.e., had no evidence of a previous CKD diagnosis).⁶

Given that Alberta is the only province in Canada to grant pharmacists the authority to access and order laboratory tests,⁸ point-of-care testing (PoCT) may present an alternative and practical way to expand CKD screening throughout the rest of Canada. However, the feasibility of offering such a service is currently unknown and needs to be assessed. Therefore, the aim of this study was to conduct a pilot study on the use of PoCT by community pharmacists to help identify CKD. The specific objectives were to 1) determine the potential recruitment rate and 2) gauge the potential number of patients identified with CKD through this process, to inform a full-scale clinical trial.

Methods

This prospective pilot study was conducted over 6 weeks (1 June to 13 July 2018) in a single community pharmacy located in Ontario, Canada. This pharmacy was chosen because it offered a multitude of services (e.g., medication review, chronic disease management with a certified diabetes educator, immunization and a pharmacogenomic screening service), had a high patient volume and had the staff (i.e., 1 pharmacist, 2-3 pharmacy students, 2 pharmacy technicians) and the facilities (i.e., a private consultation room and 3 semiprivate consultation areas) to conduct the study. The study was approved by the Research Ethics Board of Sunnybrook Health Sciences Centre.

Participants

Individuals were eligible to participate if they were:

- Adults (18 years or older)
- At risk for CKD (based upon KDIGO International Guidelines)³ because they had at least 1 of the following conditions:
  - Hypertension
  - Diabetes mellitus (type 1 or type 2)
  - Family history of stage 5 CKD (estimated glomerular filtration rate <15 mL/min or on dialysis) or hereditary kidney disease
  - Vascular disease (diagnosed cardiovascular disease, stroke/transient ischemic attack or peripheral vascular disease)
  - Multisystem disease with potential kidney involvement (systemic lupus erythematosus, rheumatoid arthritis)

Potential participants were identified at the time of presentation at the pharmacy to “drop off” or “pick up” their prescription. As part of routine care, the pharmacist systematically searched the patient’s electronic medication record for markers of any of the aforementioned conditions (e.g., metformin in the patient’s dispensing history would be considered a possible marker of diabetes). Eligible patients were subsequently invited to participate in the study and provided relevant information. They were then asked to provide written informed consent to take part.

Intervention

The study processes are detailed in Figure 1. After receiving consent, a pharmacy research student screened for CKD by conducting serum creatinine (SCr) and eGFR tests using the validated StatSensor PoCT device,⁹⁻¹⁴ as well as collecting information about the participants’ demographic characteristics and CKD status (i.e., known history, no previous history). After PoCT, participants identified as having an eGFR <60 mL/min/1.73 m² were educated by the pharmacist about CKD and were advised to make an appointment with their family physician for further testing.

Study Outcomes

The primary outcome of this pilot study was to determine the potential recruitment rate (reported as participants per month) and resources required to inform a full-scale trial of 520 participants. This number was the estimated sample size (inflated to allow for losses to follow-up) based upon information from Arora et al. (16.8% proportion of CKD and 3.3% margin of error)², 80% power and a 2 sided alpha of 0.05%, to detect a prevalence of 17% CKD among the screened population.

A secondary outcome of this study was the proportion of patients with CKD (both known and unrecognized). For the purposes of this study, CKD was defined as having an eGFR of <60 mL/min/1.73 m². CKD was then categorized into:

- “Known” CKD: Defined as having impaired kidney function tests (as defined above) and a previous diagnosis of

FIGURE 1 Flow diagram of the pilot study processes and prevalence of chronic kidney disease (known and unrecognized) among study participants

CKD as reported by the patient, physician and/or pharmacist knowledge/awareness of a previous CKD diagnosis.⁶

- “Previously unrecognized” CKD: Defined as having no previous diagnosis of CKD as reported by the patient, pharmacist or physician.⁶

Data analysis

Data were collected using Research Electronic Capture Data (REDCap) and hosted by the EPICORE Centre, University of Alberta.

Descriptive statistics were used to report the participants' demographic and clinical characteristics as well as their CKD status. Means ($\pm$ standard deviation) were used to report continuous variables, while proportions (percentage) were used to report categorical variables.

Results

During this 6-week pilot study, 108 patients were approached for participation. Of these, 89 participants consented to take part. Participants who declined to participate stated the following reasons: known CKD diagnosis ($n = 5$), needle-induced anxiety ($n = 3$), no time to spare ($n = 4$) and no interest in taking part in research ($n = 7$) (Figure 1).

Two-thirds of the participants (62.9%) were female, the median age was 67 years (interquartile range, 56-78) and 9% were current smokers (Table 1). Hypertension was the most common comorbidity (77.5%), followed by cardiovascular disease (33.7%) and diabetes (31.5%) (Table 1).

The recruitment rate was 59 patients/month. The research pharmacy student used all the available resources at the pharmacy (i.e., PoCT machine, consultation rooms). More than a tenth (11%) of the study participants had CKD. Of those, 90% had previously unrecognized CKD (Figure 1).

Discussion

Our study has demonstrated that with a recruitment rate of 59 participants per month, a full-scale trial of 520 participants is feasible over a 9-month period when utilizing a single community pharmacy and comparable resources. Furthermore, while there is evidence to support laboratory testing by pharmacists,⁷ most jurisdictions have not incorporated this into pharmacy practice.⁸ Our study demonstrated the feasibility of using PoCT at a community pharmacy setting to screen for CKD. We found that more than a tenth (11%) of the participants had CKD, and of those, 90% had previously unrecognized CKD. This finding is highly relevant to patient care, as these patients might need dosage adjustments and preventive measures to delay progression of CKD and cardiovascular risk.

Our findings are consistent with the findings of Arora and colleagues,² who analyzed data from cycle 1 of the Canadian Health Measures Survey, which ran from 2007 to 2009, to estimate the prevalence of CKD and reported that 12.5% of Canadian adults have CKD.

This pilot also uncovered a high proportion of previously unrecognized CKD. The majority (90%) of those with CKD had previously unrecognized CKD. This indicates the importance of using targeted screening approaches (screening those who are at high risk) when testing for CKD. The importance of such an approach was also highlighted by Al Hamarneh and colleagues⁶ when pharmacists used laboratory testing (eGFR and random urine albumin/creatinine ratio [ACR]) to screen for CKD in those at high risk.

TABLE 1 Demographics of the participants

Characteristic	Study participants (N = 89)
Age, mean $\pm$ SD (range)	66.75 $\pm$ 11.22 (33-94)
Female, No. (%)	56 (62.9)
Ethnicity, No. (%)	
Aboriginal/First Nation	2 (2.2)
Caucasian	71 (79.8)
Black	5 (5.6)
Hispanic	1 (1.1)
South Asian (Indian, Pakistani, Sri Lankan, Bangladeshi)	3 (3.4)
Other Asian (Far Eastern)	5 (5.6)
Arab	0
Other	2 (2.2)
Declined to answer	0
Medical history, No. (%)	
Hypertension	69 (77.5)
Diabetes	28 (31.5)
Cardiovascular disease	30 (33.7)
Stroke/transient ischemic attack (TIA)	6 (6.7)
Peripheral artery disease	6 (6.7)
Systemic lupus erythematosus	3 (3.4)
Rheumatoid arthritis	4 (4.5)
Chronic kidney disease	1 (1.1)
Family history, No. (%)	
Stage 5 chronic kidney disease	2 (2.2)
Hereditary kidney disease	0
Tobacco use status, No. (%)	
Current	8 (9.0)
Past (ceased smoking 3 or more years ago)	41 (46.1)
Never	40 (44.9)

This study is not without limitations. Selection bias may have occurred, whereby pharmacists' recruitment and patient consent may have excluded patients with known CKD, or

those patients with known CKD may have declined participation. Nevertheless, 9 out of the 89 participants had previously unrecognized CKD, which is clinically important. Recall bias is also a possibility, as the demographic information of the participants was collected via self-reporting as well as using their dispensing history. Lastly, the StatSensor device has shown good clinical concordance agreeing with laboratory references 100% and 87% of the time for >60 mL/min/1.73 m² and <60 mL/min/1.73 m², respectively.¹¹ Our original intention was to further validate the StatSensor device by having patients present to the laboratory for an ACR and serum creatinine measurements, but the logistics for this could not be worked out. Furthermore, if an ACR had been able to be performed on this sample, it might have uncovered a higher proportion of those with mild CKD, as was seen in the study by Al Hamarneh and colleagues.⁶

This pilot study may have important future implications for patient care, including optimizing medication regimens and measures to prevent and/or slow progression of CKD by minimizing risk factors such as cardiovascular events.¹⁵⁻¹⁷

Conclusion

We have demonstrated that a PoCT screening to identify CKD in a community pharmacy is feasible. Our pilot study has also uncovered a high proportion of previously unrecognized CKD. Pharmacists can play a major role in the detection and management of CKD, often otherwise undiagnosed and undertreated. This has important implications for improving patients' access to care, prognosis, cardiovascular risk and medication dosing. Furthermore, it is an important component of a full scope of pharmacy practice. ■

From the Graduate School of Health (Pharmacy), The University of Technology Sydney (Donovan, Bajorek), Broadway NSW, Australia; the EPICORE Centre, Faculty of Medicine and Dentistry (Al Hamarneh, Tsuyuki), and the Department of Pharmacology (Tsuyuki), University of Alberta, Edmonton, Alberta; and the Leslie Dan Faculty of Pharmacy (Papastergiou), University of Toronto, Toronto, Ontario. Contact jacqueline.n.donovan@student.uts.edu.au.

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ORCID iDs: Jacqueline Donovan <https://orcid.org/0000-0003-1774-1625>

Yazid N. Al Hamarneh <https://orcid.org/0000-0003-3984-3542>

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