***Evaluation of a chronic kidney disease risk assessment service in community pharmacies***

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*Short running title*

Chronic kidney disease risk assessment service in community pharmacies

*Evaluation of a chronic kidney disease risk assessment service in community pharmacies*

*Abstract*

*Aim*

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Targeted 'opportunistic' screening might be a sustainable approach for the early detection of people with undiagnosed chronic kidney disease (CKD). The aim of this study was to implement and evaluate a CKD risk assessment service in the community pharmacy setting.

*Methods*

Twenty-four pharmacies in Tasmania, Australia participated in this study. Targeted people were aged between 50-74 years, with at least one CKD risk factor. The QKidney® risk calculator was used to estimate the participants' 5-year percentage risk of developing moderate-severe CKD. Participants identified with ≥ 3% risk were referred to their general practitioner (GP) and followed-up after 9 months. Laboratory data was collected from a pathology provider. The main outcome measures were rates of GP referral uptake and of participants who underwent estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (ACR) measurement.

*Results*

We analysed data for 389 screened participants, of whom 203 (52.1%) had ≥ 3% 5-year risk of developing moderate-severe CKD and were referred to their GP. Follow-up was successful for 126 participants and showed low (27%) GP referral uptake. Analysis of the pathology data revealed suboptimal kidney testing in participants with ≥ 3% risk, with eGFR and ACR tests performed for only 52.7% and 25.1% of these participants, respectively.

*Conclusions*

There is significant scope for improving early detection of CKD via implementation of a community pharmacy-based CKD risk assessment service. However, a healthcare system that encourages inter-professional collaboration between community pharmacists and GPs, and provides a robust referral pathway is needed to optimise the effectiveness of this service.

*Keywords*

Chronic kidney disease; community pharmacy; risk assessment; screening

*Introduction*

A systematic analysis indicated that almost 500 million adults worldwide in 2010 had chronic kidney disease (CKD), the burden of which is fuelled by the epidemics of diabetes and hypertension [1]. CKD is a major risk factor for end-stage kidney disease (ESKD), cardiovascular disease (CVD) and premature death [2]. In Australia, data on the

prevalence of CKD is limited and the best available evidence to estimate the CKD burden is drawn from renal replacement therapy (RRT) data [3]. At the end of 2014, 959 Australians per million population were undergoing RRT [3], and 17% of new patients were referred late to nephrologists for the management of ESKD [4]. A retrospective study found that despite the increasing prevalence of CKD in the state of Tasmania, Australia, testing for kidney disease (i.e. serum creatinine and albuminuria) in at-risk people was suboptimal [5]. This indicates significant evidence-practice gaps and the need to improve early CKD detection.

Early diagnosis and treatment of CKD has the potential to reduce the risks of CVD and CKD progression by up to 50% [2]. Worldwide, many targeted screening programs for CKD have been conducted [6] and an Australian screening program 'Kidney Evaluation for You (KEY)' found that targeted 'opportunistic' screening might prove to be a sustainable approach [7]. Community pharmacy-based screening or risk assessment services have shown potential in detecting people at high risk of diabetes and CVD [8, 9]. Additionally, pharmacy-based screening and health promotion services help to increase public awareness. Pharmacists are highly accessible and in a good position to engage people within the community who are not aware of their risks and less likely to access general practice care [10]. Hence, pharmacists could play an important role in the early detection, referral and education of individuals at risk of CKD.

Current literature indicates that various risk assessment tools [11-13] can facilitate the early identification of people at risk of developing CKD. One such validated tool recommended by Kidney Health Australia (KHA) is the QKidney® risk calculator [13-15]. This algorithm, which estimates a person's risk of developing moderate-severe CKD (estimated glomerular filtration rate (eGFR) <45 ml/min/1.73m$^2$) over the next 5 years, was derived using the data of over 1.5 million primary care patients from 188 general practices across England and Wales [14].

The main aim of this study was to implement and evaluate a CKD risk assessment service, using the QKidney® risk calculator, in Tasmanian community pharmacies. Specific objectives were to (i) identify people at risk of developing moderate-severe CKD over the next 5 years and refer them to their general practitioner (GP) for further evaluation, and (ii) document the outcomes and challenges of implementing a CKD risk assessment service within community pharmacy.

*Methods*

The Tasmanian Health and Medical Human Research Ethics Committee (H0014258) approved this prospective cohort study. This study was conducted across 24 Tasmanian community pharmacies between February 2015 and March 2016. Geographically, 13 pharmacies were located in the south, 5 were located in the north/north east, and 6 were located in the north west/west of Tasmania. A letter of invitation explaining the purpose of the study was mailed to all (a total of 143) community pharmacies across Tasmania, and those who agreed to participate were included . The detailed recruitment process and training of community pharmacists has been described elsewhere [16]. Trained community pharmacists (n = 38), final year pharmacy students (n = 2) and a researcher (n = 1) conducted this study. Pharmacies received an incentive of $15/participant recruited. Patient participation was promoted via posters placed in the pharmacies and by pharmacists, directly approaching eligible individuals arriving at the community pharmacy.

*Risk assessment service*

Individuals eligible to participate were aged between 50-74 years, with at least one of the following self-reported risk factors: high blood pressure (BP) requiring treatment, diabetes, heart failure (HF), obesity (BMI $\geq$ 30 kg/m$^2$), current smoker, personal history of heart attack, angina, stroke or transient ischaemic attack (TIA), or family history of kidney disease. Participants who self-reported having CKD were excluded. The flow diagram for the risk assessment protocol is shown in the Supporting Information 1. After written consent was obtained, an assessment data form was used to collect participant details, such as demographics (age, gender, ethnicity, address, contact number), GP details, clinical information (smoking status, medical history, family history), and medication history (prescription and over the counter (OTC) drugs, complementary and alternative medicine (CAM)). Participants were asked to wait for at least 5 minutes before their sitting BP was measured using an electronic sphygmomanometer. The first systolic BP reading was recorded and classified as per the guidelines for the diagnosis and management of hypertension in adults by the National Heart Foundation of Australia [17]. Individual participants' height and weight were measured; subsequently, the calculated BMI was recorded and classified [18].

Collected information on age, gender, ethnicity, smoking status, diabetes (type 1 or 2), HF, high BP requiring treatment, history of heart attack, angina or TIA, family history of kidney disease, calculated BMI and measured systolic BP reading was entered into the online QKidney® risk calculator (version 2014 and 2016) [15]. Participants were given a detailed explanation of their risk assessment result, written education material on kidney disease (Supporting Information 2), and a copy of their results sheet. As per the KHA recommendations [19], participants identified with < 3% likelihood of developing moderate-severe CKD over the next 5 years (low risk) were not referred; participants with 3-15% risk (moderate risk) were encouraged to discuss the results with their GP at the next

planned visit; and participants with > 15% risk (severe risk) were asked to discuss the results with their GP within the next two weeks. We also sent a letter to the GP for each participant identified with ≥ 3% risk; the letter included information on the study, and a copy of the individual participant's assessment data form and results sheet.

*Participant follow-up*

All participants with ≥ 3% risk were followed up by telephone after 9 months. We made three attempts to contact the participant by telephone, after which we sent the survey via post. The survey included questions to establish whether the participant had: a) discussed their risk assessment results with their GP and b) undergone a 'Kidney Health Check'. According to KHA, a 'Kidney Health Check' consists of three tests: blood test for eGFR, urine test for albumin-creatinine ratio (ACR), and BP measurement [20]. The survey also included questions to determine if participants had made any changes to their lifestyle and disease management strategies as a result of participation in this study.

*Pathology data collection*

We obtained participants' follow-up laboratory data on eGFR and ACR from a major Tasmanian community-based pathology laboratory. Participant data on laboratory tests performed within one year after undergoing the risk assessment and repeated within 3 months of initial tests for participants with evidence of CKD were included in the final analysis. The pathology provider calculated the eGFR by using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula as per the revised recommendations of the Australasian Creatinine Consensus Working Group [21]. Evidence of CKD was defined as an eGFR <60 ml/min/1.73m$^2$ and ACR >3.5 mg/mmol (female) or >2.5 mg/mmol (male) [2].

*Sample size calculation*

Based on the data presented in research that developed and validated the risk assessment calculator [14], and extrapolating to an older cohort of individuals with at least one pre-existing risk factor for CKD, we estimated that 50% of the sample would have a 5-year risk of moderate-severe CKD of at least 3% (and therefore require referral). Using a 5% precision and 99% confidence level (to be 99% sure that the true percentage of the population aged between 50 and 74 years with at least one CKD risk factor that has a 5-year risk of moderate-severe CKD of at least 3% using the risk assessment calculator, is between 45% and 55%) we needed 384 eligible individuals.

*Statistical analysis*

We used the Statistical Package for Social Sciences (SPSS) version 23.0 software to perform statistical analysis. Participants with 3-15% moderate-risk were sub-categorised into 3-7.9% moderate-risk 1 and 8-15% moderate-risk 2. Descriptive statistics were calculated as mean and standard deviation (SD) for continuous variables, and percentage for categorical variables. We used a thematic approach to analyse all answers to the open-ended questions.

*Results*

*Risk assessment service*

The flow diagram for the participant recruitment process is shown in Figure 1. Out of 405 participants initially recruited in the study, we excluded 16 participants because either they did not meet the eligibility criteria or we received their data after the follow-up timeline had passed. *Table 1* shows the demographic and clinical characteristics of the 389 participants included in the final analysis. The mean (± SD) age of participants was 63.3 (± 6.4) years and 50.4% were female. More than half of our sample had two or more risk factors for CKD. Most participants (81.2%) had hypertension, 21.9% had type 2 diabetes, 15.9% had a history of heart attack, angina, stroke or TIA, and 6.7% had an immediate family history of kidney disease. Of the sample, 14.2% were smokers and 45.2% were obese. More than half of the sample (51.7%) were using CAMs, and the most common were vitamin D (21.0%), fish oil (15.5%), and magnesium (7.5%); 32.1% were using OTC drugs, and paracetamol (70.7%) was the most common of these.

The online QKidney® risk calculator identified 47.8% participants at low-risk (< 3%), 33.4% at moderate-risk 1 (3-7.9%), 11.6% at moderate-risk 2 (8-15%), and 7.2% at severe-risk (> 15%) of developing CKD in the next 5 years. Almost half (44.6%) of participants had a systolic BP ≥ 140 mmHg; 47.8% and 30.6% of participants with and without a reported diagnosis of hypertension, respectively, had a systolic BP ≥ 140mmHg.

*Participant follow-up*

Of 203 participants with ≥ 3% risk, 28 were excluded from the follow-up analysis because 12 had forgotten participating in the study, 8 had missing address/contact details and 8 withdrew during follow-up. From the remaining 175 participants, follow-up was successful for 126 (72%). Follow-up was not successful for 49 participants as these did not answer their phone (3 attempts were made) or return the completed survey that was later sent via post. The rate of successful follow-up was similar across moderate-risk 1 (71.4%), moderate-risk 2 (74.4%) and severe-risk (70.8%) categories. The success rate was highest (75.6%) amongst participants between 60-69 years and lowest (60.7%) for the age group 50-59 years. Most (70.6%) participants reported that they became aware of the risk assessment service after being approached by a pharmacist for participation.

Of 126 participants with successful follow-up, 120 (95.2%) had subsequently visited their GP and 34 (27.0%) had discussed their results. Of participants (n = 41) who provided reasons for no discussion of the results, 34% mentioned that their GP did not initiate discussion on the risk assessment results and, therefore, they did not. Of 34 participants with follow-up who had discussed results with the GP, blood test, urine test and BP checks were performed for 26, 17 and 17 participants, respectively. The percentage of these participants who underwent a complete 'Kidney Health Check' was 9 (26.5%). During follow-up, 36.4% of participants with hypertension (n = 110) and 48.1% of

participants with diabetes (n = 54), agreed that they were prompted to take better care of their hypertension and diabetes, respectively, as a result of participation. Of 14 participants with follow-up who were smokers at the time of risk assessment, 7 reported reducing the number of cigarettes smoked per day and 1 had stopped smoking.

*Pathology data analysis*

Within one year following risk assessment, eGFR and ACR testing was performed in 52.7% (n = 107) and 25.1% (n = 51), respectively, of ≥ 3% risk participants (n = 203). Simultaneous eGFR and ACR test was performed for 19.7% (n = 40) participants. *Table 2* shows the stratification of participants' eGFR and ACR data as per their moderate-severe risk categories. Six participants in the moderate-risk 1 category and one in the moderate-risk 2 category had eGFR between 45-59 ml/min/1.73m$^2$; however, repeated eGFR testing was performed for only one participant who was under the moderate-risk 1 category. Five, two and one participants in the moderate-risk 1, moderate-risk 2 and severe-risk category, respectively, had an ACR between 3.5-35 mg/mmol (female) or 2.5-25 mg/mmol (male). Again, repeated ACR testing was performed for a single participant who was in the severe-risk category.

*Withdrawal of community pharmacists*

Fourteen of 38 pharmacists withdrew from the study and the most common reason reported for withdrawal was lack of time and staff. Several pharmacists mentioned that, being the only pharmacist on-duty, they were too busy to spend 10-15 minutes per participant to conduct the risk assessment effectively.

*Discussion*

The community pharmacy-based CKD risk assessment service, with its targeting, identified a high proportion (52.2%) of people at ≥ 3% risk of developing moderate-severe CKD within 5 years. However, the follow-up analysis revealed that a low proportion (27%) of referred participants had discussed their risk results with their GP. The major reason for the low referral uptake was GPs not initiating discussion on the risk assessment results. Also, absence of an existing medical complaint might have enhanced participants' reluctance to initiate discussion [22]. Another contributing factor towards the low referral uptake could be the manner in which the results were communicated to the GP. All GPs were sent a referral letter; however, it is possible that not all of them had the opportunity to read it before the patient visit [23]. On the other hand, GPs might not have agreed with the recommendations of the risk assessment and chose not to act or deferred investigation in participants who were already overwhelmed with their existing comorbidities. Also, GPs might have over-relied on their patients to initiate discussion on the risk results [24]. In any case, the low referral uptake was a major hindrance to the efficacy of the CKD risk assessment service.

No previous studies have implemented a similar protocol in community pharmacies for CKD; hence, direct comparisons could not be made. Upon literature review, we found many pharmacy-based screening studies for

diabetes [25, 26], CVD [8] and atrial fibrillation [23], which concluded that screening in community pharmacy is effective and feasible. However, this seems to have been overstated because the GP referral uptake reported in the majority of these studies [23, 25, 26] was low and ranged from 9.1-42.4%. Only a CVD study [8] reported a high GP referral uptake (83%), although the participant loss to follow-up in this study was high (>50%). A recent systematic review investigating the effectiveness of pharmacy-based screening services found a significant proportion of screened participants do not attend their GPs for follow-up, or GPs often do not act on the referral information [10]. Additionally, a qualitative study of Australian GPs showed that most did not favour pharmacists' provision of screening services, as they believed screening to be the role of the GP and lacked confidence in the accuracy of screening tests and pharmacists' competence [27]. These findings suggest that any pharmacy-based screening services, even with a robust in-pharmacy protocol, are likely to have a low success rate unless there are close working relationships between community pharmacists and GPs [28, 29]. More specifically, there is a need to develop an innovative referral pathway which can ensure that patients who have undergone screening at community pharmacies are subjected to further investigation during their routine visit to the GP [27, 29].

A distinctive aspect of our study, compared with other pharmacy-based screening studies, was the availability of participant pathology results. The QKidney® algorithm calculates a person's risk of developing moderate-severe CKD over the next 5 years; however, this study identified 15 participants who had evidence of early CKD. For an accurate CKD diagnosis, the KHA CARI (Caring for Australasians with renal impairment) guidelines on early CKD detection recommend simultaneous and repeated ACR and eGFR measurement; otherwise, an increased incidence of both over- and under-diagnosis is likely [30]. Our pathology analysis showed that simultaneous testing was performed in only 19.7% of ≥ 3% risk participants and, although more than half of these participants had undergone eGFR testing, only about a quarter had their ACR measured. Similarly, in 2007, Jose *et al.* found that only 50.6% and 9.4% at-risk Tasmanians had serum creatinine and albuminuria measured, respectively [5]. Also, our study found that repeated ACR or eGFR measurement within three months of initial testing was performed for only 2 (13.3%) out of 15 participants with initial evidence of CKD. This suboptimal kidney testing might be attributed to the significant gaps, as identified by the AusHEART study, in Australian GPs' adherence to preventative guidelines and recognition of CKD [31].

Our pathology analysis revealed that more than half of ≥ 3% risk participants had undergone kidney testing (either eGFR or ACR measurement); however, few were aware of it. Similarly, the AusDiab study found relatively low recollection of kidney testing even in patients with CKD [32]. This suggests that information sharing by providing pharmacists access to patients' medical records and pathology data would help to prevent unnecessary screening, as well as enabling pharmacist review of medication dosing in kidney disease.

In terms of the limitations of our study, there are two community-based pathology providers in the state of Tasmania. The pathology provider from which the data for this study was collected owns approximately 80% of the Tasmanian pathology specimen collection centres and has been operating for approximately 50 years; whereas, the other provider has been operating only for the past three years. However, it is possible that relevant pathology data for some participants may have been missing.

Several barriers restricted pharmacists from continuing participation. Future studies should aim to reduce the time required to conduct risk assessment. If pharmacy assistants are trained to a) collect participant demographic and clinical data, and b) measure height and weight, then this would allow the pharmacists to focus on key aspects, which include 1) BP measurement, 2) risk assessment and 3) CKD education. Pharmacists would then need only 5-10 minutes/participant. Alternatively, the screening would only be performed by pharmacies having more than one pharmacist on duty at any time. Lastly, it is possible that kidney testing by the GP was performed as a result of other ongoing comorbidities and not as an outcome of risk assessment.

This study showed considerable scope for improving the early detection of CKD via implementation of a community pharmacy-based CKD risk assessment service. In order to improve the referral uptake, we recommend that during CKD risk assessment, community pharmacists should put emphasis on the asymptomatic nature of CKD and explain to the participant the importance of consulting their GP for a regular 'Kidney Health Check'. On the other hand, a healthcare system that encourages a close working relationship between pharmacists and GPs is needed if pharmacy-based risk assessment and screening services are to benefit the public.

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*Conflict of interest*

None.

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Figure Legend

Figure 1 Participant Recruitment process

Supporting Information 1 Flow diagram for chronic kidney disease risk assessment protocol

Supporting Information 2 Educational material on chronic kidney disease

*Table 1* Participant demographics and clinical characteristics

| Characteristics | | N | % |
|---|---|---|---|
| Total | | 389 | 100 |
| Mean age (mean ± S.D.., range) | | 63.3 ± 6.4, 50-74 | |
| Gender | | | |
| Female | | 196 | 50.4 |
| Male | | 193 | 49.6 |
| Ethnicity | | | |
| White or not stated | | 383 | 98.5 |
| Indian | | 1 | .3 |
| Other Asian | | 2 | .5 |
| Other ethnic group | | 3 | .8 |
| Region (n = 381) | | | |
| South | | 205 | 52.7 |
| North/north east | | 89 | 22.9 |
| North west/west | | 87 | 22.4 |
| Smoking status | | | |
| Non-smoker | | 218 | 56.0 |
| Ex-smoker | | 116 | 29.8 |
| Light smoker (less than 10 cigarettes/day) | | 29 | 7.5 |
| Moderate smoker (10 to 19 cigarettes/day) | | 11 | 2.8 |
| Heavy smoker (20 or over cigarettes/day) | | 15 | 3.9 |
| Diabetes | | | |
| Type 1 | | 5 | 1.3 |
| Type 2 | | 85 | 21.9 |
| Heart failure | | 9 | 2.3 |
| High blood pressure requiring treatment | | 316 | 81.2 |
| History of a heart attack, angina, stroke or transient ischaemic stroke | | 62 | 15.9 |
| Immediate family* history of kidney disease (*mother, father, brothers or sisters) | | 26 | 6.7 |
| Body mass index (kg/m$^2$) | | | |
| Underweight | <18.5 | 2 | .5 |
| Healthy | 18.5-24.9 | 56 | 14.4 |
| Overweight | 25-29.9 | 155 | 39.8 |
| Obese | ≥30 | 176 | 45.2 |
| Systolic blood pressure (mmHg) (n = 386) | | | |
| Optimal | <120 | 50 | 12.9 |
| Normal | 120-129 | 51 | 13.1 |
| High normal | 130-139 | 113 | 29.0 |
| Grade 1 (mild) hypertension | 140-159 | 128 | 32.9 |
| Grade 2 (moderate) hypertension | 160-179 | 38 | 9.8 |
| Grade 3 (severe) hypertension | ≥180 | 6 | 1.5 |
| Qkidney risk range (%) | | | |
| Risk category | Percentage risk | | |
| Low | <3 | 186 | 47.8 |
| Moderate 1 | 3-7.9 | 130 | 33.4 |
| Moderate 2 | 8-15 | 45 | 11.6 |
| Severe | >15 | 28 | 7.2 |

*Table 2* Stratification of participants' estimated glomerular filtration rate and albumin creatinine ratio data as per their moderate-severe risk categories

| | | | Risk categories | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Total | | Moderate-risk 1 (3-7.9%) | | Moderate-risk 2 (8-15%) | | Severe-risk (> 15%) | |
| | N | % | N | % | N | % | N | % |
| Estimated glomerular filtration rate (eGFR) (ml/min/1.73m2) (n = 107) | | | | | | | | |
| >90 | 36 | 33.6 | 22 | 61.1 | 10 | 27.8 | 4 | 11.1 |
| 60-89 | 64 | 59.8 | 40 | 62.5 | 14 | 21.9 | 10 | 15.6 |
| 45-59 | 7 | 6.5 | 6 | 85.7 | 1 | 14.3 | - | - |
| 30-44 | - | - | - | - | - | - | - | - |
| 15-30 | - | - | - | - | - | - | - | - |
| <15 | - | - | - | - | - | - | - | - |
| Albumin creatinine ratio (ACR) (mg/mmol) (n = 51) | | | | | | | | |
| <3.5, female; <2.5, male | 43 | 84.3 | 26 | 60.5 | 9 | 20.9 | 8 | 18.6 |
| 3.5-35, female; 2.5-25, male | 8 | 15.7 | 5 | 62.5 | 2 | 25 | 1 | 12.5 |
| >35, female; >25, male | - | | - | - | - | - | - | - |

Figure 1 Participant recruitment process