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QUALITY IMPROVEMENT

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Evaluating the feasibility and acceptability of home-based urinalysis for albumin-creatinine ratio with smartphone technology: A quality improvement project

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Abstract

Background: Despite albumin-creatinine ratio (urine) testing being recommended for detection of chronic kidney disease among adults with diabetes, testing rates are suboptimal.

Aim: We implemented and evaluated a quality improvement project in an inner-city diabetes population in London, UK to assess the feasibility and acceptability of implementing novel home-based urinalysis using smartphone technology.

Methods: After eligible patients were identified and consented, testing kits were sent to the patient's home. Test results and patient feedback were collected through the smartphone application. Focus group discussions were conducted to evaluate primary care staff perspectives on uptake and delivery of the service.

Results: In total 2370 patients agreed to take part. Of these, 1244 completed the test (61% of those eligible) and of these, 465 (37%) had clinically significant albuminuria. 98% of patients found the test easy or very easy to use. Staff in primary care found the service to be beneficial for patients, and reported ease of set up and minimal administrative processes. Concerns regarding barriers among patients with lower digital literacy and non-English speakers were raised although these concerns were not substantiated.

Conclusion: Home-based albumin-creatinine ratio urine testing may improve the testing rates of people with diabetes at higher risk of chronic kidney disease. This is important post-pandemic, as healthcare services are trying to return to pre-pandemic levels of care. The study also found that the use of smartphone technology in an underserved (deprived) community is feasible, despite reservations about levels of digital literacy and possible language barriers. Further evaluation of effectiveness and costs is required.

KEYWORDS

chronic kidney disease, primary care, quality improvement, remote care, urinalysis

BACKGROUND

Chronic Kidney Disease (CKD) affects 1 in 10 adults in the UK, with most recent estimates of annual cost to the UK national health service (NHS) of £1.45 billion (1.3% of total healthcare expenditure) (Kerr et al., 2012). Diabetes is one of the most common causes of CKD, where diabetic-related damage to the kidneys is a significant risk factor for the development of end-stage kidney disease (Macisaac et al., 2014). In the UK, 3.9 million people are known to have diabetes and are 1.5 times more likely to need renal replacement therapy, compared with the general population (Diabetes, 2019).

LITERATURE REVIEW

The National Institute for Care and Excellence (NICE) clinical guidelines (2021) recommend that all individuals at risk of developing CKD receive annual blood tests to measure the estimated glomerular filtration rate (eGFR) and also urinalysis of albumin: creatinine ratio (ACR). Despite evidence to support the use of early screening of ACR as an effective preventative strategy for identifying those at risk of progressive CKD, and subsequent referral to secondary care (Larmour et al., 2015), the UK National Diabetes Audit (2020) reported only 51.8% ACR compliance, with the likelihood that rates dropped further due to the coronavirus disease 2019 (COVID-19) pandemic. The low rate has been attributed to patients forgetting to bring a urine sample to their GP appointment, not knowing a sample was required, and a lack of awareness of the importance of ACR testing (Willison et al., 2016), as well as primary care staff not being aware of the importance of an ACR result to stage CKD.

In the era of telemedicine, particularly following the widespread disruption to healthcare services during the pandemic, there has been an increased use in digital health tools for home-based screening (e.g., Leddy et al., 2019; Weigel et al., 2021). Healthy. io is the first CE-accredited and FDA-approved home-based urine test that uses smartphone technology for clinical-grade urinalysis with an application (App) and a smartphone camera. Healthy.io combines convenience and accuracy, helping to increase accessibility and enhance the early detection of CKD-related complications. Healthy.io has previously demonstrated promise as a safe and convenient strategy to overcome impracticalities of traditional urinalysis in a single site in the UK during the pandemic, facilitating care among vulnerable groups (Stauss et al., 2022).

Moreover, financial modelling by York Economic York Health Economics Consortium (YHEC) confirmed that adopting Healthy.io's service for people with diabetes unreceptive to traditional testing is cost-effective from 1 year (Shore et al., 2020). When adopted across England, the modelling estimated 3463 cases of end-stage kidney disease, and 523 deaths would be prevented over 5 years due to an additional 22,946 cases of CKD being diagnosed. This would potentially save the NHS £209,445,072. However, the feasibility and acceptability of implementing Healthy.io technology among at risk populations has not been extensively evaluated across the UK, especially perspectives of both staff and patients.

Here we describe a novel quality improvement intervention involving collaboration between General Practices (surgeries) in one inner-city area in the UK, with the aim to increase the number of at-risk patients completing an ACR test in the UK.

AIMS AND OBJECTIVES

The aim of this quality improvement project was to evaluate the feasibility and acceptability of using smartphone technology for home-based urine testing in people with diabetes at risk of CKD, in one Clinical Commissioning Group (CCG). CCGs are clinically led groups which include all the GP Practices in one small geographical area. The CCGs work with patients and healthcare professionals in partnership with local communities and local authorities.

This geographical area has high levels of deprivation with Index of Multiple Deprivation (IMD) scores showing a large proportion of the area in the highest deprived (top 10%) areas in the UK. However, there are now considerably fewer areas of deprivation in 2019 compared with 2015 (London Datastore, 2019). 65% of the population in this area has English as their main language.

The specific objectives were to:

1. Utilise quality improvement methodology to implement a new approach to ACR testing in one CCG across multiple Practices in East London.
2. Evaluate the effectiveness of using home smartphone urinalysis test to increase uptake of ACR testing in those with diabetes who had not returned an ACR sample in the past 12 months.
3. To evaluate patient and staff perspectives of the home-testing service acceptability and feasibility.

We employed the reporting framework suggested by the Standards for Quality Improvement Reporting Excellence (SQUIRE) publication guidelines for reporting healthcare quality improvement research (Davidoff et al., 2008).

METHODS

Study setting

This quality improvement project was planned to run between October 2020 and September 2021 but was extended until December 2021 due to the COVID-19 pandemic. The local CCG serves an estimated 17,000 people living with diabetes mellitus with only 2% of adults recorded as having kidney disease, partly due to a very young population. In the UK, around 20% of people receiving dialysis have diabetes, yet in this CCG it rises to over 40% (Renal Registry, 2018). One reason for the high number of people receiving dialysis in this CCG is because of the diverse community, with one of

the largest Bangladeshi communities in the country. As there is a low percentage of people recorded as having CKD but a higher-than-average prevalence of those receiving dialysis due to diabetes, identification and management of CKD is critical.

The project team comprised a project lead (kidney nurse), project assistant (nurse), one person with lived experience of diabetes, one CCG representative (nurse), one diabetes doctor, one kidney doctor, and one kidney nurse.

Information Governance and Information Communication Technology Committee approvals from the CCG were sought and obtained by Healthy.io. Ethical approval for the interviews with Practice staff was obtained from the University.

Patient recruitment

The process of contacting General Practices was led by the project team. Despite the COVID-19 restrictions and vaccination rollout, we recruited six Practices. The recruitment of patients to the project was undertaken by Practices, supported by the technology company (Healthy.io). Electronic health record data were used by Practices to identify eligible participants. The inclusion criteria were registered patients, ≥18 years, living with diabetes, with no recorded ACR in the past 12 months. Patients were excluded from the project if they were pregnant, care home residents, patients with a catheter, and/or patients currently being cared for on an end-of-life care pathway.

Eligible patients were sent an SMS (text) from their Practice with information about the project. Patients then received a telephone call from the Healthy.io patient team to provide further information about the project and obtain consent to share their data for evaluation purposes. During the telephone call, a translation service for patients that did not understand English well was used. In addition, patient team callers that also spoke a number of local languages were recruited. Translation of written information about the nature of the project was not undertaken, but local feedback suggested that translated written information is not useful, as people in the local population are not always able to read in their first language. However translation should always be considered, and it is one of the recommendations going forward.

Patient flow and intervention

Consenting patients received the home testing kit delivered to their home address and Healthy.io provided telephone support to patients regarding downloading of the App and urine testing kit where required. Patients were contacted via SMS and telephone call if the test hadn't been completed within 1 week, with the caller verifying that the kit had been received and offering personalised support to download the App and conduct the test, and then at subsequent intervals as appropriate.

The remote testing required two components: (1) the Healthy.io smartphone App and (2) the Minuteful Kidney testing kit. The Minuteful Kidney urine testing kit includes one urine (collapsible) beaker, one urinalysis dipstick and a colour collaboration board (similar to a urine dipstick). To conduct the home test, patients follow the instructions provided in the App, collect urine, dip the dipstick, place the dipstick on the colour board and then scan the dipstick colour board with their phone camera. Urinalysis results are presented in the App to the patient and automatically uploaded to a secure Practice Egton Medical Information Systems (EMIS) list. All results are displayed to the patient in the App. Patients with abnormal results (>3 mg/mmol) were notified via the App that their GP will follow-up regarding the abnormal result and were advised to wait to be contacted by their GP rather than booking an appointment. Patients were also presented with a short video from an NHS GP with information about the result, reassurance on next steps and signposting to NHS resources. Figure 1 shows a summary of the patient pathway.

Outcomes

The primary outcome was to assess the number of completed ACR results received compared with previous data, although a comparison was

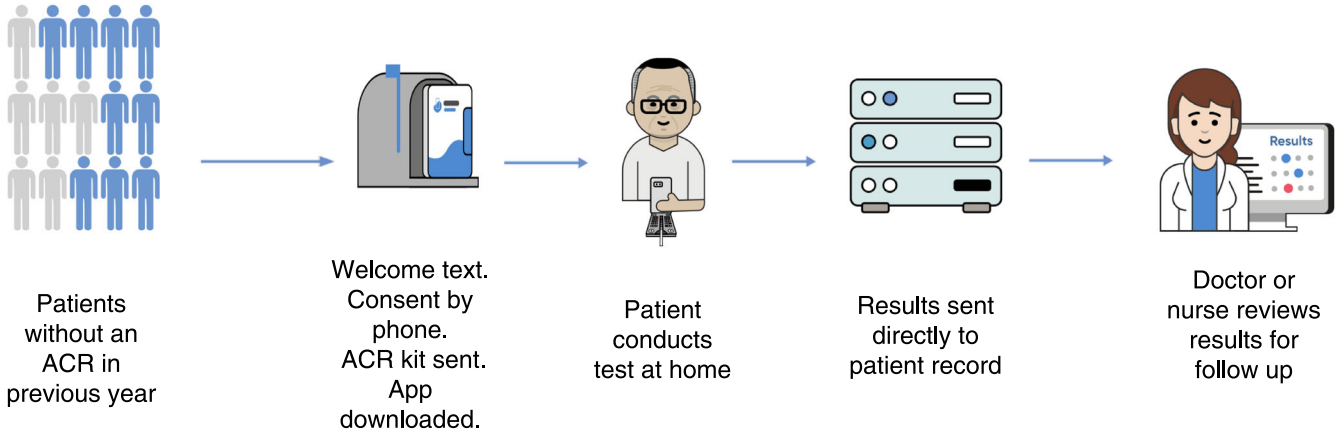

FIGURE 1 Patient pathway.

difficult, because of the pandemic meant that many patients were not able to visit their Practice in 2020. Secondary measures were to 1) evaluate patients satisfaction using the home-testing urinalysis technology as measured by the in-App survey and 2) explore Practice staff perspectives and experiences of implementing the Healthy.io technology.

Data collection

Patients

The primary outcome of this project was to increase the number of people in this CCG with an up-to-date ACR test. Based on the cohort size that had not returned an ACR test, it was estimated from other studies (Shore et al., 2020) that 30% of patients would complete a home-based ACR test. Data from patients consenting to participate in the project and completing their home-testing urinalysis were collated including a number of years since the last ACR test and the number of patients with abnormal ACR results across each Practice.

Additionally, quantitative data on patients' perspectives of the home-testing kit were assessed via a short online questionnaire within the App.

Practitioners

All six participating Practices were contacted between May and September 2021 to participate in an online focus group discussion. Because of the pandemic, only two online discussions were conducted at the end of the project period, at two separate Practice sites. Participants ($n = 4$) included one GP, one Practice manager and two nurses. Discussions were led by two members of the university team (one of whom was a kidney nurse) and aimed to evaluate staff's motivation for participating in the project, experiences integrating and using the technology, and the sustainability of the home-testing technology. Focus groups were audio recorded and transcribed.

Statistical analysis

Quantitative data collected from patient ACR tests and patient surveys were used to produce descriptive statistics (see Table 1). Qualitative focus group data were thematically analysed using discourse analysis (Potter, 2004), fitting the focus group participants and primary care setting.

RESULTS

Feasibility

The final sample included data returned from four Practice sites. Table 1 displays the frequency and results of tests carried out across four Practices. Abnormal ACR results are >3 mg/mmol. Data were not collected from two Practices, as the study was paused in one Practice and there were challenges with collecting data in the other, due to the pandemic. The total cohort consisted of 2370 eligible patients who provided consent and were enroled into the project. In total, 1244 (61% patients) completed the home test. We do not know why only 61% returned the test even though they had consented, but forgetting, not understanding what was required or not having enough time are possible reasons. Results indicate that of patients completing the test, 465 (37%) patients had clinically significant albuminuria levels. This is comparable with other study results that have used traditional ACR testing (Sana et al., 2020).

Acceptability: Patient satisfaction

Patient feedback was collected in the App. In total, 640 patients provided feedback, with 94% of patients finding the test easy or very easy to use and having no problems using the device. Only 13% reported that they would prefer to have their ACR tested in the clinic. 82% reported that they would recommend the service to a friend or colleague.

Feedback from patients identified by Practice staff indicated that patients found the service simple and easy to use. Patients reported to staff that the technology reduces the burden of taking time off work, making an appointment, and attending the Practice with a urine sample. However, there were concerns raised by staff around language and understanding, as patients who requested the urinalysis kit but did not use it (39%) reported that the service was confusing. Staff reported that these patients were predominantly older

TABLE 1 Urinalysis test results across Practice sites.

Years since last ACR	Practice 1		Practice 2		Practice 3		Practice 4	
	Abnormal >3 mg/mmol	Normal	Abnormal >3 mg/mmol	Normal	Abnormal >3 mg/mmol	Normal	Abnormal >3 mg/mmol	Normal
<2	32	42	5	7	24	40	1	0
2+	25	28	9	21	30	63	17	11
3+	10	13	6	6	16	52	2	9
4+	1	1	2	6	15	20	0	3
5+	7	5	0	1	11	14	0	4

populations and may not have been comfortable using smartphone Apps and/or had a limited understanding of the English language.

Staff perspectives

Due to the impact of the COVID-19 pandemic, only two of the six Practices participated in the online focus group discussion. Analysis of focus group data produced three sub-themes aligned to the service: motivating factors, satisfaction, and sustainability.

Motivating factors

Interest in the project was initiated by Practice staff, either Practice managers, GPs or Practice nurses who had a specific interest in diabetes and renal care. Staff noted that the backdrop of the pandemic enabled them to use the App due to patients' limited access to in-person appointments. Staff felt that the technology was beneficial to the Practice, particularly the ease of set-up from Healthy.io and the minimal administrative processes required from Practice staff. Overall, staff felt that home-testing technology significantly saved time. Moreover, the ease of receiving patient ACR results directly into patient records via Healthy.io enabled easy identification of patients requiring a follow-up appointment. However, it was reported that some staff members needed reminders to follow up with their patients who required a second urine test.

Satisfaction among staff

Practice staff found that the technology and service were very easy to set up. The only issue identified was the challenged following patients up with abnormal ACR results who required a second urine test. Some staff members within the Practice team were reported to as being uncertain about following up on abnormal results and required reminders.

Sustainability of the service

Nurses reported that they would be happy to continue using the technology and service long-term and were aware about the potential cost implications and benefits to patients and the Practice. Staff noted that the GP would need to carefully consider the cost using the test kits compared with employing another staff member to conduct the same test using traditional, in-person methods. We do not have follow-up data on those who did not have an ACR test using the smartphone App and kit, but Practice staff would follow up annually as per usual Practice.

DISCUSSION

The aim of the present multi-site project was to utilise a quality improvement methodology to implement a novel approach to ACR testing. We found that the use of smartphone urinalysis kits delivered to a patient's home increased rates of albuminuria screening amongst those who had not returned a test over the previous year. While only five Practice sites fully participated, the number of patients completing the home testing significantly exceeded our estimates. The numbers of people with diabetes untested for ACR in the original six Practices were 1165 in 2018/19; 1335 in 2019/20; 1820 in 2020/21 (start of pandemic); and 1125 in 2021/22 (during this study). Therefore, the number of untested patients during the year of our study was less than pre-pandemic levels.

Those who completed home testing were highly satisfied, indicating that home-based screening of ACR may be a useful method to improve rates of albuminuria screening and reduce the risks of kidney disease.

Overall, the project resulted in a relatively high uptake (61%) of eligible patients completing the home-testing and identified 37% of patients with clinically significant albuminuria results. This is promising compared with previous studies implementing ACR Practice screening among patients at risk of CKD which described suboptimal rates of screening ranging from 22% to 30% (Litvin et al., 2016; Peralta et al., 2017). Mendu et al. (2014) achieved a measured improvement in annual ACR screening of 73% across 1 year by implementing a chronic kidney disease checklist embedded into primary care to improve adherence to CKD management guidelines. Mendu et al.'s (2014) findings, in combination with our quality improvement findings, further demonstrate the potential benefit of embedding home-based testing into a CKD management toolkit as a novel strategy to increase adherence to ACR screening.

Consistent with previous research, the healthy.io smartphone App and home-based urinalysis testing kit have previously demonstrated high levels of patient satisfaction (Leddy et al., 2019; Stauss et al., 2022). Compared with Leddy et al. (2019) who reported that 21% of patients would prefer to test in the Practice, we found that only 13% would prefer to attend the Practice. This increased preference for at home-testing may be explained by the pandemic and potential concerns attending their GP and a general trend towards remote services. Positive feedback was largely focused on convenience and ease of use. However, it was noted that some patients not completing the home test found the service to be confusing, highlighting the need for clearer communication and transparent information for patients.

The care of patients during the COVID-19 pandemic has been challenging, and this was reflected in our difficultly engaging Practices alongside the vaccine rollout and restricted healthcare services during the project. A potential challenge to implementing the services identified by Practice staff was potential barriers to

language among non-English speakers and digital literacy. Such findings reinforce the need to bridge the gap in the 'digital divide' (Chesser et al., 2016). Future delivery of Healthy. io services should carefully consider the barriers and facilitators to accessibility and develop strategies to support less technologically literate patients and those with language barriers (Addotey-Delove et al., 2020).

The cost of the service is £14.50 per patient, which is inclusive of a) system integration to ensure that the results are entered directly into the GP Practice system, b) kit delivery and postage, c) App licenses for all users, d) personalised support for all users to complete the test (including the chasing up as described above). Economic modelling (Shore et al., 2020) asserted that in people with diabetes who do not usually return standard ACR tests, the technology is associated with cost saving of around £2000 (2320 euros) per person over a lifetime, due to increased CKD diagnosis and reduced progression to end-stage kidney disease.

Strengths and limitations

Despite the small number of Practices involved in this project, the use of qualitative feedback provided a rich understanding of implementing home-testing ACR screening and valuable insights into the specific needs of patients within the CCG. Although the number of comments was limited, all Practices expressed enthusiasm for incorporating the home urine testing kit into routine nephrology care.

There were several limitations that must be acknowledged. This study is a quality improvement initiative rather than a randomised controlled trial, with no comparator group. Efficacy testing of using smartphone urinalysis to increase uptake of ACR testing was not assessed in the current project due to time constraints and challenges obtaining appropriate ethical approval during the COVID-19 pandemic. Future research should identify patients' understanding of CKD and risk factors and could assess Patient Activation to understand why patients may accept or decline urinalysis testing. As we did not record patient's reason for opting out, we recognise that patients in the present project were self-selected and therefore may report more favourably on the service (Rygh et al., 2012).

The feasibility and acceptability of the Healthy.io services may be limited by digital inclusion among individuals with limited digital skills, accessibility, and lack of connectivity to digital infrastructure (The Strategy Unit, 2020). In addition to increasing ACR adherence, facilitating digital inclusion can provided several opportunities for improved self-management of conditions among patients, ease caring responsibilities, and reduce pressure on primary care health services. Therefore, continued effort is needed to identify barriers to digital inclusion within Healthy.io services and embed strategies such as translation software and staff training to bridge the digital divide (Chesser et al., 2019).

Quality improvement

At the end of the project in early 2022, the above findings were discussed with patients, Practice staff and the Healthy.io service providers to identify improvements to the patient pathway. The following issues were considered, and changes were implemented:

1. Patients raised concerns about the SMS messaged they received informing them about the healthy.io service, stating that poor wording and the use of a short bit.ly link drove scepticism among patients that the service may potentially be a scam. The SMS text that includes the bit.ly link has now been changed.
2. Patients reported uncertainty about *who* Healthy.io were and their relationship with their Practice, particularly as patients were contacted by Healthy.io via telephone out with their local area. Healthy.io aims to re-train call centre staff to ensure the team can reinforce clearly to patients the role of Healthy.io as a company and their relationship with Practices. Additionally, the outbound phone number is now associated with each project has a local area code.
3. Patients reported that on receiving abnormal results, they felt there was a lack of guidance from both the App and their GP about next steps in their care. Healthy.io has since begun work with Kidney Care UK to produce patient-facing content to ensure that all communication with patients is transparent and effective. Additionally, the App will now embed an auto-playing recording at the end of the App flow for patients who receive an abnormal ACR result, reassuring and prompting patients to arrange a second test before drawing any conclusions due to normal biological variability. Furthermore, patients are signposted to additional resources from Diabetes UK and Kidney Care UK.
4. To address barriers to accessibility and uptake among patients including language and digital literacy, Healthy.io have begun targeted recruitment of multilingual onboarding staff to ensure that they can offer support in eight of the most widely used languages used by staff including Bengali, Urdu and Punjabi. Additionally, Healthy.io has partnered with Essential Accessibility (https://www.essentialaccessibility.com/), who support Healthy.io with regular evaluation of the accessibility and inclusivity of services and recommend changes such as ensuring text size within the App reflects a user's settings.

IMPLICATIONS FOR PRACTICE

This project has demonstrated that home-based urinalysis is feasible and acceptable to diverse communities, and may improve compliance to ACR testing. It is recommended that the service be rolled out further in primary care. Although the direct costs of implementing the technology at scale might be considerable, the long-term costs may be offset if the future burden of CKD is reduced.

CONCLUSION

The current process must undergo further evaluation to confidently promote a change of practice, including whether smartphone testing could be a true surrogate for urine ACR and adequate for starting management such as medication. The results of this project call for definitive studies to address the effectiveness and costing of this home-based urinalysis in a controlled longitudinal study and on a wider scale.

AUTHOR CONTRIBUTIONS

Nicola Thomas: Principal Project Leader, conceived study, participated in design and coordination, read and approved the final manuscript. **Carolyn Hill**: Participated in design and coordination, undertook interviews, helped to draft manuscript, read, and approved the final manuscript. **Catriona Ewart**: Helped to draft manuscript and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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