



Innovative Medical Technology Overview

Minuteful Kidney for home testing of albumin-to-creatinine ratio (ACR)

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Executive Summary

Minuteful Kidney is a home urine test for measuring albumin-to-creatinine ratio (ACR) for use, in primary care, in patients at risk of chronic kidney disease (CKD). The aim of the technology is to improve uptake of ACR testing in patients with conditions including diabetes and high blood pressure in order to promote early identification and treatment of CKD, and reduce rates of end-stage renal disease (ESRD). Audit data indicates that rates of relevant annual ACR testing are as low as 54% in people with diabetes.

Four single arm observational studies in the UK focused on people with diabetes who were not following standard ACR testing. There was variability in the proportion of eligible patients agreeing to take part in home testing (32% to 91%). A high proportion of patients contacted agreed to participate (ranging from 72% to 78%) and, of those consenting to receive the test kit, between 71% and 89% went on to complete the test.

- The main reasons for non-participation were not having access to a smartphone and preferring to have the test at the GP surgery.
- Across studies, the proportion of patients recording a positive (abnormal or high abnormal) test result ranged from 23% to 25%.
- Patient satisfaction amongst those using the test was high. Between 92% and 98% of users found it easy or very easy to use and 84% to 97% expressed that their preference was for home testing.
- Two studies provided views of healthcare staff. The challenges in following up abnormal test results in patients who did not routinely engage with primary care was noted.
- No safety issues were identified.

Two cost-consequence analyses based on one model concluded that MinuteKidney is likely to be cost saving when compared with usual care. These findings rely on assumptions of test results being appropriately followed up with repeat testing, monitoring and, where required, treatment to prevent ESRD.

To derive benefit from using the technology in the long term, adequate and appropriate follow up is needed for patients with positive tests.

Technology and Innovative aspect

MinuteKidney is a smartphone-based diagnostic home urine test for the semi-quantitative detection of microalbumin and creatinine, and the qualitative measurement of the ratio between them (the ACR). The technology is CE marked as an in vitro diagnostic for self testing.¹ FDA approval documents indicate substantial equivalence of the device to existing reagent strips for semi-quantitative ACR testing, based on levels of agreement between tests on a range of samples.²

The test allows people with diabetes, high blood pressure or other risk factors for CKD to test themselves at home and receive immediate results.

The technology consists of an ACR test kit and a mobile application containing image recognition software which allows a smartphone to act as an ACR urine strip analyser using a software algorithm, computer vision and colourimetric analysis.

The ACR test kit is delivered to the patient's home and contains all the single-use equipment needed for in vitro ACR testing, including:¹

- a urine collection cup
- an individually wrapped ACR urine reagent strip (dipstick)
- an absorbent pad to remove excess liquid from the reagent strip, and
- a colour-board to enable image recognition.

The patient also receives a text message from their healthcare provider inviting them to download the ACR app. The app can be installed on Android and iOS smartphones that meet minimum hardware criteria. The app guides the patient through each step of the testing process using text, video and audio support.

The test process takes about 3-5 minutes and includes the following steps:

1. collect a urine sample using the urine collection cup

2. dip the reagent strip into the sample for 1 second, remove any excess liquid with the absorbent pad and place the strip on the colour-board
3. wait 1 minute (60 seconds) then scan the colour-board for the software algorithm to analyse the scanned image, and
4. ACR results will appear on the app when the test is complete.

The app automatically and securely sends the analysed results to the referring clinician through the patient's electronic medical record (EMR) for follow up, if required.

Minuteful Kidney offers patients the option, which may be more convenient, to carry out semi-quantitative urine ACR testing within their own home, compared with standard of care where patients are required to bring a urine sample to their general practice for it to be sent to a lab for analysis. Results are shared immediately with a clinician through the EMR. This allows real-time results to be reviewed and followed up.¹

Patient group

ACR testing is recommended for adults at risk of CKD. This includes people with diabetes, hypertension and other risk factors including acute kidney injury, cardiovascular disease, structural renal tract disease, recurrent renal calculi or prostatic hypertrophy, multisystem diseases with potential kidney involvement, family history of end-stage kidney disease, opportunistic detection of haematuria and prescribed drugs that have an effect on kidney function.¹

The most recent Scottish Diabetes Survey (2020) estimates that there were over 317,000 people with a diagnosis of diabetes in Scotland in 2019.³ In 2019, around a quarter of the population of Scotland aged 16 years and over had raised blood pressure.⁴ Based on data from a limited number of practices in 2018/19, the prevalence of CKD in Scotland was 3.08 per 100 registered population.⁵

Despite guidance on ACR testing, the National CKD Audit (2017) found that only 54% of people with diabetes have relevant annual urinary ACR tests. For other groups (such as those with hypertension), ACR rates are below 30%.¹

Current practice: comparators and use in pathway of care

ACR testing is recommended for people with diabetes and those without diabetes with a glomerular filtration rate (GFR) of less than 60 ml/min/1.73 m². The presence of protein in the urine should be tested for by measuring ACR and testing for blood in the urine using a reagent strip.

Current standard of care for urine ACR testing involves asking the patient to collect a urine sample at home which they bring back to the healthcare provider who sends it for laboratory analysis.¹ A repeat test is required for any first ACR reading between 3 mg/mmol and 70 mg/mmol. A confirmed ACR reading of ≥ 3 mg/mmol is considered clinically important. Reagent strips are not recommended unless they can specifically measure albumin at low concentrations and express the results as an ACR, like Minuteful Kidney.

The developers intention is that the Minuteful Kidney would be used instead of existing tests to detect microalbuminuria in people with diabetes or high blood pressure who are at risk of kidney disease and have not taken up standard testing in primary care.¹

Many patients in these at risk groups will require monitoring of blood pressure so either a visit to the primary care setting is still necessary or home blood pressure monitoring must also be in place.

Product performance and cost implications: published data

A single arm observational study conducted in a large GP partnership in NHS England evaluated the uptake and use of Minuteful Kidney. Data from this evaluation was used to develop a cost-consequence analysis.⁶

People with diabetes (n=2,196) who had not had an ACR measurement reported in the previous 18 months were identified and contacted to secure their verbal consent to have a test sent to their home and receive a text message linking them to the Minuteful Kidney app. Of these, 695 (32%) agreed and entered the home testing protocol. Reasons for not taking part in the study included; not owning a smartphone (35%), lack of confidence with digital technology or self testing (16%), having just provided a sample or already having an appointment booked (11%) and concerns about information security (2%).

Of those sent a test, 499 (72%) completed it and returned a result within one month. In a survey of this group to which 170 (34%) patients responded, 92% of people found the test easy or very easy to use with only 1% finding it difficult or very difficult to use. Only 3% said they preferred testing at the GP surgery.

A cost-consequence model compared home ACR self testing plus standard care with standard care in people with diabetes. A lifetime time horizon was applied with primary and secondary care costs (2017/18 prices) being discounted at 3.5% per year.⁷

The main assumptions in the model base case were:

- patients who were non-compliant with testing continued to be non-compliant
- 32% of patients non-compliant with standard testing would consent for home testing
- the rate of home testing in those consenting to it remained at 72%
- the sensitivity of all testing was 87% and specificity was 88%
- the prevalence of albuminuria was 20%
- 100% of patients with albuminuria develop CKD
- 29% of all patients would present with symptoms of CKD each year
- patients with CKD are assumed to receive treatment, and
- treatment for CKD slows progression to ESRD and reduces associated cardiovascular complications including stroke or myocardial infarction.

Costs included:

- administrative time for booking follow-up appointments relating to abnormal test results
- GP time for reviewing test results with patients
- annual treatment costs for patients with CKD, and
- direct costs of ESRD including dialysis and transplant.

The total cost of the home testing kit was £11 whilst the total cost of the standard care semi-quantitative test was £5.

The average per patient costs in the base case model were £49,172 for self testing and £51,180 for standard care. This cost saving of £2,008 over a lifetime was as a result of increased rate of CKD diagnosis and reduced progression to ESRD. The direction of findings was robust to two scenarios. The cost saving was reduced to £619 per patient if patients who were non-compliant reverted to average compliance rate (54%, based on National CKD Audit) after the first year. If the diagnostic accuracy of the home testing was based on the lowest measures in the literature and the standard testing set to the highest level in the literature, the lifetime cost saving was reduced to £1,851 per person.

Product performance and cost implications: implementation data

A mixed methods evaluation of implementation of MinuteKidney across nine primary care practices in the Leeds and Bradford area was reported in June 2021.⁸ The evaluation was conducted by York Health Economics Consortium and included data on uptake of the service, patient and staff views and analysis of costs.

Implementation of the service began in autumn 2020 and data collection for the evaluation ended in March 2021.

There were 2,020 patients with diabetes who had been identified by the practices as not having had an ACR test in the past 12 months and who consented to have their details passed to the developers (Healthy.io). Based on information from seven of the nine practices, this represents 91% of the total eligible population. From this group of patients, 80% (1,622) were successfully contacted by Healthy.io and 72% (1,163) of those contacted agreed to be sent a test kit. The most common reason for declining was not having a smartphone (41%). Around 26% of those declining the offer preferred to take, were planning to take or had recently taken a urine sample to their GP. Of the patients who agreed to participate, 87% (1,012) completed the test. This represents approximately 46% of all eligible patients.

A comparison was made between the characteristics of patients declining to participate following contact with Healthy.io (n=459) and a subgroup of those agreeing to participate (n=513) who consented for their individual data to be used. There was a significant difference in the distribution of age, sex and index of multiple deprivation (IMD) decile between the participating groups when compared with those who declined. There was a greater proportion of males (59%) in the participating group than in the declining group (52%). Females represented a greater proportion of those in the declining group (48%) when compared with the participating group (41%). The younger age ranges were more represented in the participating group compared with the declining group. There was a lower proportion of people from IMD decile 1 (most deprived) and a higher proportion of people from IMD decile 5 in the participating group compared with those declining. The likelihood of performing the test following agreement to participate was not significantly associated with age, sex or IMD decile.

Of the 1,012 patients who completed the home test, 23% (235) had an abnormal result (ACR ≥ 3.4 mg/mmol). Of this group, 77 (33%) patients had a high abnormal result (ACR > 33.9 mg/mmol). There was no significant association between the level of deprivation and the likelihood of an abnormal test result (p=0.23).

Amongst patients who completed the test and sent feedback using a satisfaction questionnaire within the app (n=742), 95% found the ACR home-based urine test either easy or very easy to use, with only nine patients (1.2%) noting it to be difficult or very difficult to use. Ninety five per cent of respondents reported having no problems using the device. 76% (565) expressed a preference for home testing and over 90% of respondents gave a high score (≥ 7 out of 10) expressing strong likelihood of recommending the test to a friend or colleague.

Staff from five of the nine practices responded to an online survey. There were six respondents; three GPs and three managerial staff. Five of the six respondents thought that it had been quite easy to implement the digital home ACR testing in their practice, with one (a practice manager) reporting that it had been quite difficult. All respondents considered that the home test would increase uptake of ACR testing. Four of the six respondents recorded that their involvement in the implementation had improved their understanding of CKD management. Issues raised in open comments included:

- time investment in setting up systems
- implications of subsequent workload following up on abnormal tests results
- raises profile of important test, and
- intervention does not reach and is not suitable for all patients.

The cost-consequence model described in the published evidence section above was applied to data from the evaluation to examine the impact on costs and outcomes. The total cost of home testing was £14.50 per patient compared with the standard test cost of £5.42. The number of patients entering the model was 2,020, average age 58 and adherence with home ACR testing was set at 50% of those who consented to be contacted by Healthy.io. The comparative costs over a range of time horizons is displayed in *Table 1*. The economic modelling estimated the cost savings over the patients' lifetime to be around £1,262. Savings remained in scenario analyses exploring the effect of 15% of those non-adherent to standard care becoming adherent. Lifetime incremental cost saving was £849 per patient. The cost savings derive from an estimated increase in the total number of CKD diagnoses and a consequent reduction in future cases of ESRD.

The model incorporates the assumption that abnormal tests are followed up and appropriate treatment is commenced such that reduction in cases of ESRD is achieved.

Table 1: costs over different time horizons

	Home ACR Testing	Standard Care	Incremental
1 Year time horizon			
Costs per patient	£491	£493	-£2
Total costs per cohort	£991,785	£996,139	-£4,354
5 year time horizon			
Costs per patient	£5,067	£5,392	-£325
Total costs per cohort	£10,235,152	£10,892,154	-£657,001
10 year time horizon			
Costs per patient	£14,069	£14,878	-£808
Total costs per cohort	£28,420,357	£30,052,945	-£1,632,589
Lifetime time horizon			

Costs per patient	£37,994	£39,256	-£1,262
Total costs per cohort	£76,748,340	£79,296,607	-£2,548,267

A Nuffield Trust evaluation of MinuteKidney implementation in primary care was conducted as part of a project (Care City) to test digital health innovations within three east London GP practices between March 2020 and July 2020.⁹

There were 811 eligible patients diagnosed with type 1 or type 2 diabetes who had not undertaken an ACR test in the previous 12 months. Of these, 712 were contacted about the home test. Consent was received from 508 patients and 369 (72.6%) completed the test. The proportion of people accepting and consenting to the test decreased as age increased. The main reasons cited for declining the test were that they did not have a smartphone (34%) or would rather bring a sample to the surgery (19%). Abnormal or high abnormal findings were identified in 91 patients (25%).

Ninety eight percent of respondents to a user satisfaction survey (260/369) expressed that they found the test easy or very easy to use and the majority (90%) reported that they preferred home testing.

Implementation staff reported that a few patients had found the kit and/or app complicated to use and several patients had contacted practice staff for support with downloading the app or reported needing support from family or friends.

The total cost of implementing the ACR test was £8,687. This included the home test cost of £12 per patient which covers all activity related to setting up, implementing and delivering the pathway. Additional costs of administration and following up abnormal results brought the per patient cost to £17. It was noted that implementation of the MinuteKidney test required little support from the Care City team, with the developers (Healthy.io) responsible for contacting the eligible patients to introduce the app and testing kit, providing information and supporting the download, as well as posting the kits to patients.

Practice staff viewed the test positively in terms of helping them meet their local and national diabetes targets and ensuring that patients received appropriate care.

Staff commented on the potential impact of the COVID-19 pandemic on the implementation with one person suggesting that patients may have had greater access to assistance from friends and family members to help them conduct the test than usual times and another suggesting that the pandemic meant reduced capacity of staff to follow up abnormal results.

One of the findings of the study was a need to consider how best to inform patients that the test company will be contacting them. Despite receiving a text message from their practice several patients called the practice to ensure the contact they received was legitimate.

The greatest challenge to implementation was around engaging patients for follow up of abnormal tests.

A project to implement MinuteKidney across a primary care network in Dorset ran for 12 weeks in 2020. GP practices identified 1,483 patients with diabetes who had not had an ACR finding recorded in the previous 12 months (Personal Communication, D Brand, Healthy.io. 15 October 2021). It is unclear how many agreed to have contact with Healthy.io but of 1,214 successfully contacted by the company, 78% (968) agreed to have a kit sent to their home. Of those sent the kit, 89% (865) performed the home test with 207 (24%) recording a positive

result. Of those using the test 80% completed a survey with 94% noting the test to be easy or very easy to use and 84% stating a preference for home testing.

An audit was conducted around follow up of positive tests. Few details of how and when the audit was conducted were available but the findings may have important implications for the cost effectiveness of the technology since it relies on reducing cases of ESRD and the comorbidities associated with the later stages of CKD. Learning points from the audit included:

- Minuteful Kidney testing needs to be embedded within existing practice systems with named clinical or administrative staff responsible for follow up
- obtaining and managing follow-up urine samples from patients with a positive home test can be challenging and requires robust processes integrated with laboratory systems
- results of follow-up tests need to be acted upon with appropriate communication with patients, and referral and treatment where necessary, and
- liaison with renal and diabetes teams to ensure practice staff have training in the importance of kidney screening and management CKD is advisable.

Equality considerations

The reliance of this technology on patients having a smartphone and being confident and competent in using the app may mean that particular groups of patients are disadvantaged. In addition, those with poor manual dexterity (including that associated with diabetic neuropathy), or visual or auditory impairment may find the system difficult to use. Patients whose first language is not English may experience difficulties using the test unless translations are made available.

Recommendations for research

Research focus should be on the extent to which the follow up of abnormal home tests translates into long term health benefits for patients. This would include quantifying the patient journey in terms of the proportion of tests accurately followed up, and the proportion of patients participating in ongoing monitoring, receiving appropriate treatment or being offered referral to secondary care.

Qualitative exploration of patients' experience of receiving an abnormal test result at home should also be explored.

Conclusions

Minuteful Kidney provides an option for patients at risk of CKD who are overdue for an ACR measurement to conduct the test at home. Patients who consent to participate generally find the test to be convenient and easy to use and most prefer home testing. There is potential for the technology to reduce healthcare costs if follow up and treatment of patients with abnormal results is completed such that rates of CKD can be reduced and numbers of patients experiencing ESRD minimised. The main risk from using the technology is that abnormal findings are not acted upon. Follow up of this seldom reached patient group may be

challenging and robust tracking of patients with abnormal home ACR test results will be needed to realise potential quality of life benefits and cost savings.

References

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What is an IMTO?

An IMTO provides a high-level summary of the evidence surrounding health and care innovation in Scotland. IMTOs may include:

- a description of the available evidence surrounding the technology, based on the framework for health technology assessment (HTA)
- a review of local evaluation(s) undertaken within NHSScotland, and
- commentary on the development of the evidence base.

The purpose of an IMTO is to raise awareness of promising innovations and to assist local decision making by health and care colleagues. Further information about the IMTO process can be found on the SHTG [webpage](#).