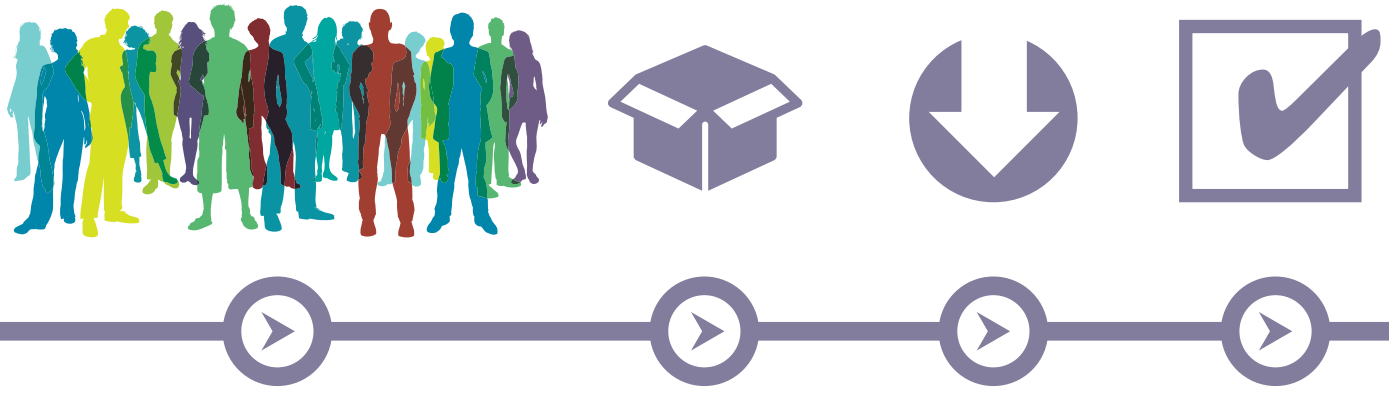
Figure 1
Steps in the Minuteful Kidney Implementation Research



There's No Place Like

Exploring a home-based test for kidney disease

By Cori Grant, PhD, MBA, MS, and Joshua J. Gregoire, MS, MPH, RN, NEA-BC

The coronavirus pandemic exacerbated existing barriers to care, contributing to the delay or neglect of important preventive services like routine screening. On the other hand, the pandemic also brought much-needed attention to how technology can help remove barriers and bridge care gaps by shifting healthcare to patients' homes.[1]

Diabetes and high blood pressure are the leading causes of chronic kidney disease (CKD). Approximately 37 million Americans have CKD, about 15% of adults, but nearly 90% of them do not know it.[2] This makes screening essential.

Clinical guidelines for people with type 2 diabetes (T2DM) recommend screening annually for kidney disease using the urine albumin-to-creatinine ratio (uACR).[3] Screening is also universally recommended at diagnosis for patients with hypertension (HTN) to establish a baseline for monitoring renal function and to inform dose adjustments for medications that rely on renal excretion. Organizations such as the American Society of Nephrology and National Kidney Foundation recommend screening for albuminuria in patients with HTN, although specific recommendations vary.[4]

Still, screening remains suboptimal, even where guidelines are consistent and unambiguous. A recent AMGA analysis of electronic health record (EHR) data from 24 geographically diverse member organizations found only 45% of patients with T2DM and 17% with HTN had uACR measured in the past year.[5] For a disease that is often asymptomatic, improving early detection of CKD and intervention to avoid progression are important.

AMGA partnered with Valley Medical Group in New Jersey to study the implementation and uptake of the first home-based uACR test using a smartphone to receive U.S. Food and Drug Administration (FDA) clearance: Minuteful Kidney, from Healthy.io. It uses the smartphone camera to accurately interpret a urine test strip, comparing colors to a printed reference card.

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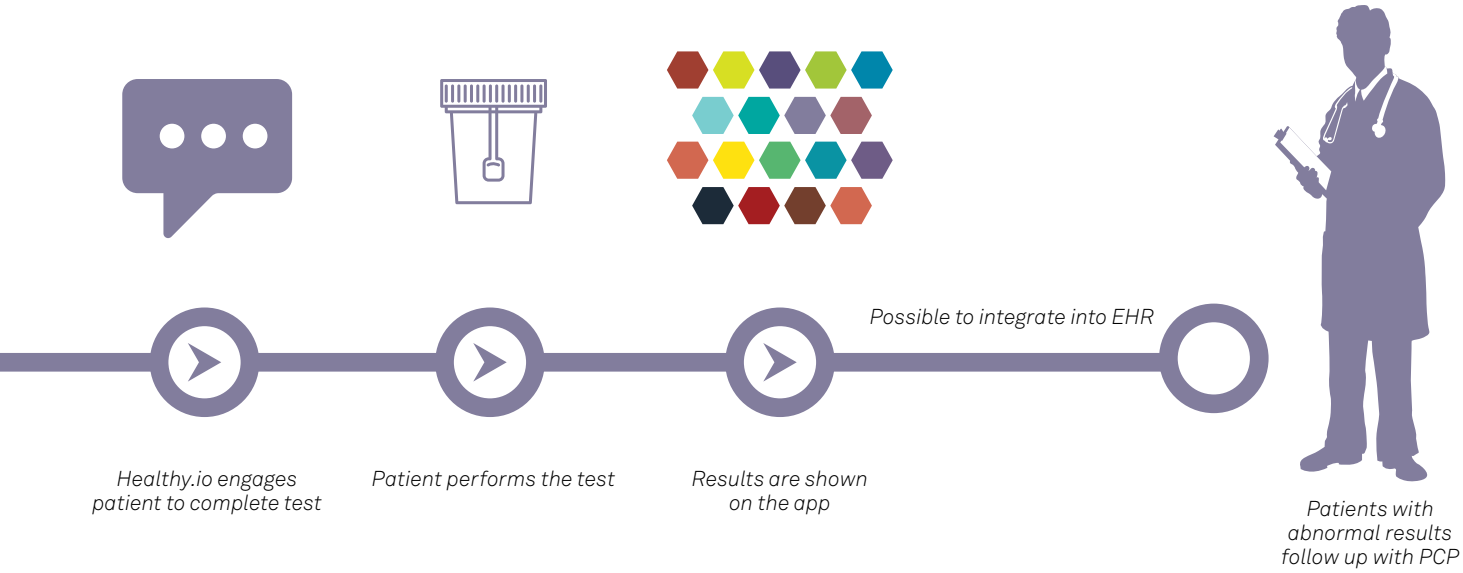

Home

Methods

Patients were included if they had a diagnosis of T2DM or HTN, did not have a uACR documented in their health record for the prior 12 months, and did not have a diagnosis of CKD. A test kit was sent to the patient's home including a specimen cup, a dipstick, and a reference card that was used by an app on a smartphone to determine the result. Within minutes, the patient had their result, which was transmitted to Healthy.io and then faxed to the patient's primary care provider (PCP). No lab was needed. Instructions on how to take the test, general information about kidney health, and the contact information for the Healthy.io help desk were sent with the test and Healthy.io conducted outreach via text messages, phone calls, letters, and emails. The communication was staggered over three months and served to encourage patients to complete the test.

This semi-quantitative test provides one of three results: normal (uACR <30 mg/g), abnormal (30–300), and high abnormal (>300). Patients also receive a 10-question survey that they complete in the app. The steps in this process are displayed in Figure 1.

The proportion of eligible T2DM and HTN patients who completed the test was assessed. Patients also received a 10-question survey about their experience with the

Minuteful Kidney screening tool that they completed in the app and a roundtable discussion was held with PCPs to understand their experience with implementation, documentation of results, and follow-up.

Results

A total of 2,840 patients met the eligibility criteria, and 49% completed the at-home test. Among those who were eligible, 86% had a diagnosis of HTN, 10% T2DM, and 4% both HTN and T2DM. Sixty percent of the tests were in the normal range, 36% abnormal, and 4% high abnormal. The rate of completion among those with HTN and T2DM were 50% and 47%, respectively. The average age of participants was 66 (range: 23–100). Among eligible patients, 348 (12%) declined participation. The top two reasons for opting out were a lack of interest (43%) and lack of access to a smartphone (18%).

Among patients who completed the test, 93% rated it easy or very easy to complete, and 95% said they would recommend it to a friend. Ninety-seven percent of participants indicated that they would follow up with their PCP.

The Minuteful Kidney test app and kit allow patients to test themselves at home for signs of CKD and receive immediate clinical results.

The roundtable with PCPs focused on communication with patients, the implementation process and coordination with Healthy.io, integration into clinical workflow, and advantages and disadvantages of at-home testing.

Examples of the mitigation strategies identified during the study:

- Allow PCPs to review the list of potential patients and identify appropriate patients for screening.
- Discuss the need for screening with the patient in advance (can be done via phone call) and request records if the screen was completed elsewhere.
- Send a letter to the patient from the healthcare organization (HCO) letting them know that Healthy.io is acting on the HCO's behalf; include a designated phone number at the HCO that patients can call with questions and provide Q&As to the staff answering the phone.
- To prevent unnecessary concern, provide clear communication to the patient about the results and when and how they should follow up if needed. Include detail about the chance of a false-positive result.
- Educate office staff in primary care practices and specialists and other clinicians across the organization; provide them with FAQs so they can respond to questions if needed; tell specialists where to find results in the EHR.
- Educate PCPs about the importance of uACR screening among patients with HTN; increase PCP education on guidelines and recommendations.

Discussion

Minuteful Kidney proved to be a useful home-based screening tool, as nearly half of the participants completed the test, with 40% returning abnormal results requiring follow-up. Patients found it easy to use, and over time, workflows were designed to improve communication between patients and their care teams to ensure successful screening and follow-up. Home-based tests are especially useful for patients receiving telehealth visits and those who live in remote areas. Tools like this facilitate a population health approach to chronic disease identification, treatment, and management.

Several barriers to clinician engagement were identified. First,

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use of the tool to date has largely been driven by payers, often without giving PCPs and care teams an opportunity to discuss the rationale for the test with the patient prior to the arrival of the kit. As a result, it makes sense financially as well as clinically for provider organizations to stay ahead of the curve, as they take on more financial risk for their patient population.

PCPs were unsure of whether to proceed with screening among people with HTN due to ambiguous evidence and guidance, especially when faced with staffing shortages and limited time. This resulted in reluctance to screen this patient population. Targeted PCP and clinic staff education with time for discussion may help mitigate uncertainty and reinforce a shared purpose of providing the best care possible for patients. More universal advocacy for uACR testing in patients with HTN, as we see in Europe, may be helpful in the United States.

Despite the barriers, many clinicians eventually embraced the use of Minuteful Kidney, and patients reported satisfaction with the home-based test. Home-based screening using tools like Minuteful Kidney may help HCOs satisfy the kidney health evaluation measure for people with diabetes (urine microalbumin testing), which is helpful for care gap closure, especially if patients are unable to leave a urine specimen when seen in the office. It also serves as a feasible alternative to office-based tests when patients lack transportation or prefer to manage their health from home. To ensure success, communication between patients and PCPs is paramount. Patients need to be informed about the test and understand its limitations, while providers need to be informed and supportive of patients using the test.

Additional research is needed to understand the impact of home-based tests on CKD disease detection and subsequent management. GRJ

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